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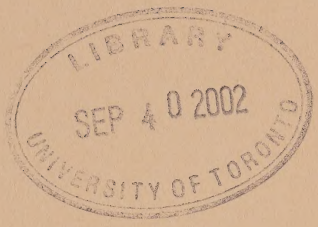
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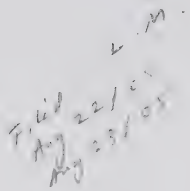
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2004- AMENDMENTS

FOOD AND DRUGS ACT

AND

FOOD AND DRUG REGULATIONS



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2003- AMENDMENTS

FOOD AND DRUGS ACT

AND

FOOD AND DRUG REGULATIONS

Filed Feb. 1/03 2003
EOP

Catalogue No. - 2003 Amendments: H41-1/2003-1E

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DEPARTMENTAL CONSOLIDATION

OF THE

FOOD AND DRUGS ACT

AND OF THE

FOOD AND DRUG REGULATIONS

WITH AMENDMENTS TO DECEMBER 31, 2006

●

ISSUED BY

DEPARTMENT OF HEALTH

●

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AN ACT RESPECTING FOOD, DRUGS, COSMETICS AND THERAPEUTIC DEVICES

Short Title

Short Title

1. This Act may be cited as the Food and Drugs Act.

Interpretation

Definitions

2. In this Act,

"advertisement" ***«publicité»*** ***ou «annonce»***

"advertisement" includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device;

"analyst" ***«analyste»***

"analyst" means a person designated as an analyst for the purpose of the enforcement of this Act under section 28 or under section 13 of the *Canadian Food Inspection Agency Act*;

"contraceptive device" ***«moyen anti-conceptionnel»***

"contraceptive device" means any instrument, apparatus, contrivance or substance other than a drug, that is manufactured, sold or represented for use in the prevention of conception;

"cosmetic" ***«cosmétique»***

"cosmetic" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes;

"Department" ***«ministère»***

"Department" means the Department of Health;

"device" ***«instrument»***

"device" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) restoring, correcting or modifying a body function or the body structure of human beings or animals,

(c) the diagnosis of pregnancy in human beings or animals, or

(d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,

and includes a contraceptive device but does not include a drug;

"drug" ***«drogue»***

"drug" includes any substance or mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) restoring, correcting or modifying organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept;

"food" ***«aliment»***

"food" includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever;

"inspector" ***«inspecteur»***

"inspector" means any person designated as an inspector for the purpose of the enforcement of this Act under subsection 22(1) or under section 13 of the *Canadian Food Inspection Agency Act*;

"label" ***«étiquette»***

"label" includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package;

"Minister" ***«Ministre»***

"Minister" means the Minister of Health;

"package" ***«emballage»***

"package" includes any thing in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed;

"prescribed" ***«version anglaise seulement»***

"prescribed" means prescribed by the regulations;

"sell" «vendre»

"sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration;

"unsanitary conditions" «conditions non hygiéniques»

"unsanitary conditions" means such conditions or circumstances as might contaminate with dirt or filth, or render injurious to health, a food, drug or cosmetic.

PART I
Foods, Drugs, Cosmetics and Devices

General

Prohibited advertising

3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Prohibited label or advertisement where sale made

(2) No person shall sell any food, drug, cosmetic or device

(a) that is represented by label, or

(b) that the person advertises to the general public

as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Unauthorized advertising of contraceptive device prohibited

(3) Except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception.

Food

Prohibited sales of food

4. No person shall sell an article of food that

(a) has in or on it any poisonous or harmful substance;

(b) is unfit for human consumption;

(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;

(d) is adulterated; or

(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Deception etc., regarding food

5. (1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Food labelled or packaged in contravention of regulations

(2) An article of food that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Importation and interprovincial movement of food

6. (1) Where a standard for a food has been prescribed, no person shall

(a) import into Canada,

(b) send, convey or receive for conveyance from one province to another, or

(c) have in possession for the purpose of sending or conveying from one province to another

any article that is intended for sale and that is likely to be mistaken for that food unless the article complies with the prescribed standard.

Not applicable to carriers

(2) Paragraphs (1)(b) and (c) do not apply to an operator of a conveyance that is used to carry an article or to a carrier of an article whose sole concern, in respect of the article, is the conveyance of the article unless the operator or carrier could, with reasonable diligence, have ascertained that the conveying or receiving for conveyance of the article or the possession of the article for the purpose of conveyance would be in contravention of subsection (1).

Labelling, etc., of food that is imported or moved interprovincially

(3) Where a standard for a food has been prescribed, no person shall label, package, sell or advertise any article that

(a) has been imported into Canada,

(b) has been sent or conveyed from one province to another, or

(c) is intended to be sent or conveyed from one province to another

in such a manner that it is likely to be mistaken for that food unless the article complies with the prescribed standard.

Governor in Council may identify standard or portion thereof

6.1 (1) The Governor in Council may, by regulation, identify a standard prescribed for a food, or any portion of the standard, as being necessary to prevent injury to the health of the consumer or purchaser of the food.

Where standard or portion thereof is identified

(2) Where a standard or any portion of a standard prescribed for a food is identified by the Governor in Council pursuant to subsection (1), no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that food unless the article complies with the standard or portion of a standard so identified.

Unsanitary manufacture, etc., of food

7. No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions.

Drugs

Prohibited sales of drugs

8. No person shall sell any drug that

(a) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or

(b) is adulterated.

Deception, etc., regarding drugs

9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Drug labelled or packaged in contravention of regulations

(2) A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Where standard prescribed for drug

10. (1) Where a standard has been prescribed for a drug, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for that drug, unless the substance complies with the prescribed standard.

Trade standards

(2) Where a standard has not been prescribed for a drug, but a standard for the drug is contained in any publication referred to in Schedule B, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for that drug, unless the substance complies with the standard.

Where no prescribed or trade standard

(3) Where a standard for a drug has not been prescribed and no standard for the drug is contained in any publication referred to in Schedule B, no person shall sell the drug, unless

(a) it is in accordance with the professed standard under which it is sold; and

(b) it does not resemble, in a manner likely to deceive, any drug for which a standard has been prescribed or is contained in any publication referred to in Schedule B.

Unsanitary manufacture etc., of drug

11. No person shall manufacture, prepare, preserve, package or store for sale any drug under unsanitary conditions.

Drugs not to be sold unless safe manufacture indicated

12. No person shall sell any drug described in Schedule C or D unless the Minister has, in prescribed form and manner, indicated that the premises in which the drug was manufactured and the process and conditions of manufacture therein are suitable to ensure that the drug will not be unsafe for use.

Drugs not to be sold unless safe batch indicated

13. No person shall sell any drug described in Schedule E unless the Minister has, in prescribed form and manner, indicated that the batch from which the drug was taken is not unsafe for use.

Samples

14. (1) No person shall distribute or cause to be distributed any drug as a sample.

Exception

(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.

Schedule F drugs not to be sold

15. No person shall sell any drug described in Schedule F.

Cosmetics

Prohibited sales of cosmetics

16. No person shall sell any cosmetic that

(a) has in or on it any substance that may cause injury to the health of the user when the cosmetic is used,

(i) according to the directions on the label or accompanying the cosmetic, or

(ii) for such purposes and by such methods of use as are customary or usual therefor;

(b) consists in whole or in part of any filthy or decomposed substance or of any foreign matter; or

(c) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Where standard prescribed for cosmetic

17. Where a standard has been prescribed for a cosmetic, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that cosmetic, unless the article complies with the prescribed standard.

Unsanitary conditions

18. No person shall manufacture, prepare, preserve, package or store for sale any cosmetic under unsanitary conditions.

Devices

Prohibited sales of devices

19. No person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.

Deception, etc., regarding devices

20. (1) No person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

Devices labelled or packaged in contravention of regulations

(2) A device that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Where standard prescribed for device

21. Where a standard has been prescribed for a device, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that device, unless the article complies with the prescribed standard.

PART II

ADMINISTRATION AND ENFORCEMENT

Inspection, Seizure and Forfeiture

Inspectors

22. (1) The Minister may designate any person as an inspector for the purpose of the enforcement of this Act.

Certificate to be produced

(2) An inspector shall be given a certificate in a form established by the Minister or the President of the Canadian Food Inspection Agency attesting to the inspector's designation and, on entering any place pursuant to subsection 23(1), an inspector shall, if so required, produce the certificate to the person in charge of that place.

Powers of inspectors

23. (1) Subject to subsection (1.1), an inspector may at any reasonable time enter any place where the inspector believes on reasonable grounds any article to which this Act or the regulations apply is manufactured, prepared, preserved, packaged or stored, and may

(a) examine any such article and take samples thereof, and examine anything that the inspector believes on reasonable grounds is used or capable of being used for that manufacture, preparation, preservation, packaging or storing;

(a.1) enter any conveyance that the inspector believes on reasonable grounds is used to carry any article to which section 6 or 6.1 applies and examine any such article found therein and take samples thereof;

(b) open and examine any receptacle or package that the inspector believes on reasonable grounds contains any article to which this Act or the regulations apply;

(c) examine and make copies of, or extracts from, any books, documents or other records found in any place referred to in this subsection that the inspector believes on reasonable grounds contain any information relevant to the enforcement of this Act with respect to any article to which this Act or the regulations apply; and

(d) seize and detain for such time as may be necessary any article by means of or in relation to which the inspector believes on reasonable grounds any provision of this Act or the regulations has been contravened.

Warrant required to enter dwelling-house

(1.1) Where any place mentioned in subsection (1) is a dwelling-house, an inspector may not enter that dwelling-house without the consent of the occupant except under the authority of a warrant issued under subsection (1.2).

Authority to issue warrant

(1.2) Where on ex parte application a justice of the peace is satisfied by information on oath

(a) that the conditions for entry described in subsection (1) exist in relation to a dwelling-house,

(b) that entry to the dwelling-house is necessary for any purpose relating to the administration or enforcement of this Act, and

(c) that entry to the dwelling-house has been refused or that there are reasonable grounds for believing that entry thereto will be refused,

the justice of the peace may issue a warrant under his hand authorizing the inspector named therein to enter that dwelling-house subject to such conditions as may be specified in the warrant.

Use of force

(1.3) In executing a warrant issued under subsection (1.2), the inspector named therein shall not use force unless the inspector is accompanied by a peace officer and the use of force has been specifically authorized in the warrant.

Definition of "article to which this Act or the regulations apply"

(2) In subsection (1), "article to which this Act or the regulations apply" includes

(a) any food, drug, cosmetic or device;

(b) anything used for the manufacture, preparation, preservation, packaging or storing thereof; and

(c) any labelling or advertising material.

Assistance and information to be given inspector

(3) The owner or person in charge of a place entered by an inspector pursuant to subsection (1) and every person found therein shall give the inspector all reasonable assistance and furnish the inspector with any information he may reasonably require.

Obstruction and false statements

24. (1) No person shall obstruct or hinder, or knowingly make any false or misleading statement either orally or in writing to, an inspector while the inspector is engaged in carrying out his duties or functions under this Act or the regulations.

Interference

(2) Except with the authority of an inspector, no person shall remove, alter or interfere in any way with anything seized under this Part.

Storage and removal

25. Any article seized under this Part may, at the option of an inspector, be kept or stored in the building or place where it was seized or, at the direction of an inspector, the article may be removed to any other proper place.

Release of seized articles

26. An inspector who has seized any article under this Part shall release it when he is satisfied that all the provisions of this Act and the regulations with respect thereto have been complied with.

Destruction with consent

27. (1) Where an inspector has seized an article under this Part and its owner or the person in whose possession the article was at the time of seizure consents to its destruction, the article is thereupon forfeited to Her Majesty and may be destroyed or otherwise disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Forfeiture

(2) Where a person has been convicted of a contravention of this Act or the regulations, the court or judge may order that any article by means of or in relation to which the offence was committed, and any thing of a similar nature belonging to or in the possession of the person or found with the article, be forfeited. On the making of the order, the article and thing are forfeited to Her Majesty and may be disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Order for forfeiture on application of inspector

(3) Without prejudice to subsection (2), a judge of a superior court of the province in which any article is seized under this Part may, on the application of an inspector and on such notice to such persons as the judge directs, order that the article and any thing of a similar nature found with it be forfeited to Her Majesty, if the judge finds, after making such inquiry as the judge considers necessary, that the article is one by means of or in relation to which any of the provisions of this Act or the regulations have been contravened. On the making of the order, the article or thing may be disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Analysis

Analysts

28. The Minister may designate any person as an analyst for the purpose of the enforcement of this Act.

Analysis and examination

29. (1) An inspector may submit to an analyst, for analysis or examination, any article seized by the inspector, any sample therefrom or any sample taken by the inspector.

Certificate or report

(2) An analyst who has made an analysis or examination may issue a certificate or report setting out the results of the analysis or examination.

Regulations

30. (1) The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular, but without restricting the generality of the foregoing, may make regulations

(a) declaring that any food or drug or class of food or drugs is adulterated if any prescribed substance or class of substances is present therein or has been added thereto or extracted or omitted therefrom;

(b) respecting
  (i) the labelling and packaging and the offering, exposing and advertising for sale of food, drugs, cosmetics and devices,
  (ii) the size, dimensions, fill and other specifications of packages of food, drugs, cosmetics and devices,
  (iii) the sale or the conditions of sale of any food, drug, cosmetic or device, and
  (iv) the use of any substance as an ingredient in any food, drug, cosmetic or device,
  to prevent the purchaser or consumer thereof from being deceived or misled in respect of the design, construction, performance, intended use, quantity, character, value, composition, merit or safety thereof, or to prevent injury to the health of the purchaser or consumer;

(c) prescribing standards of composition, strength, potency, purity, quality or other property of any article of food, drug, cosmetic or device;

(d) respecting the importation of foods, drugs, cosmetics and devices in order to ensure compliance with this Act and the regulations;

(e) respecting the method of manufacture, preparation, preserving, packing, storing and testing of any food, drug, cosmetic or device in the interest of, or for the prevention of injury to, the health of the purchaser or consumer;

(f) requiring persons who sell food, drugs, cosmetics or devices to maintain such books and records as the Governor in Council considers necessary for the proper enforcement and administration of this Act and the regulations;

(g) respecting the form and manner of the Minister's indication under section 12, including the fees payable therefor, and prescribing what premises or what processes or conditions of manufacture, including qualifications of technical staff, shall or shall not be deemed to be suitable for the purposes of that section;

(h) requiring manufacturers of any drugs described in Schedule E to submit test portions of any batch of those drugs and respecting the form and manner of the Minister's indication under section 13, including the fees payable therefor;

(i) respecting the powers and duties of inspectors and analysts and the taking of samples and the seizure, detention, forfeiture and disposition of articles;

(j) exempting any food, drug, cosmetic or device from all or any of the provisions of this Act and prescribing the conditions of the exemption;

(k) prescribing forms for the purposes of this Act and the regulations;

(l) providing for the analysis of food, drugs or cosmetics other than for the purposes of this Act and prescribing a tariff of fees to be paid for that analysis;

(l.1) respecting the assessment of the effect on the environment or on human life and health of the release into the environment of any food, drug, cosmetic or device, and the measures to take before importing or selling any such food, drug, cosmetic or device;

(m) adding anything to any of the schedules, in the interest of, or for the prevention of injury to, the health of the purchaser or consumer, or deleting anything therefrom;

(n) respecting the distribution or the conditions of distribution of samples of any drug;

(o) respecting
  (i) the method of manufacture, preparation, preserving, packing, labelling, storing and testing of any new drug, and
  (ii) the sale or the conditions of sale of any new drug,
  and defining for the purposes of this Act the expression "new drug"; and

(p) authorizing the advertising to the general public of contraceptive devices and drugs manufactured, sold or represented for use in the prevention of conception and prescribing the circumstances and conditions under which, and the persons by whom, those devices and drugs may be so advertised.

Regulations respecting drugs manufactured outside Canada

(2) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations governing, regulating or prohibiting

(a) the importation into Canada of any drug or class of drugs manufactured outside Canada, or
(b) the distribution or sale in Canada, or the offering, exposing or having in possession for sale in Canada, of any drug or class of drugs manufactured outside Canada,

as the Governor in Council deems necessary for the protection of the public in relation to the safety and quality of any such drug or class of drugs.

Regulations re the North American Free Trade Agreement and WTO Agreement

(3) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations as the Governor in Council deems necessary for the purpose of implementing, in relation to drugs, Article 1711 of the North American Free Trade Agreement or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement.

Definitions

(4) In subsection (3),

"North American Free Trade Agreement"

"North American Free Trade Agreement" has the meaning given to the word "Agreement" by subsection 2(1) of the *North American Free Trade Agreement Implementation Act*;

"WTO Agreement"

"WTO Agreement" has the meaning given to the word "Agreement" by subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.

Regulations to implement the General Council Decision

(5) Without limiting or restricting the authority conferred by any other provisions of this Act or any of its Parts for carrying into effect the purposes of this Act or any of its Parts, the Governor in Council may make any regulations that the Governor in Council considers necessary for the purpose of implementing the General Council Decision.

Definitions

(6) The definitions in this subsection apply in this subsection and in subsection (5).

"General Council"

"General Council" means the General Council of the WTO established by paragraph 2 of Article IV of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

"General Council Decision"

"General Council Decision" means the decision of the General Council of August 30, 2003 respecting Article 31 of the TRIPS Agreement, including the interpretation of that decision in the General Council Chairperson's statement of that date.

"TRIPS Agreement"

"TRIPS Agreement" means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

"WTO"

"WTO" means the World Trade Organization established by Article I of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

Interim Orders

Interim orders

30.1 (1) The Minister may make an interim order that contains any provision that may be contained in a regulation made under this Act if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment.

(2) An interim order has effect from the time that it is made but ceases to have effect on the earliest of

(a) 14 days after it is made, unless it is approved by the Governor in Council,
(b) the day on which it is repealed,
(c) the day on which a regulation made under this Act, that has the same effect as the interim order, comes into force, and
(d) one year after the interim order is made or any shorter period that may be specified in the interim order.

Contravention of unpublished order

(3) No person shall be convicted of an offence consisting of a contravention of an interim order that, at the time of the alleged contravention, had not been published in the *Canada Gazette* unless it is proved that, at the time of the alleged contravention, the person had been notified of the interim order or reasonable steps had been taken to bring the purport of the interim order to the notice of those persons likely to be affected by it.

Exemption from STATUTORY INSTRUMENTS ACT

(4) An interim order

(a) is exempt from the application of sections 3, 5 and 11 of the *Statutory Instruments Act*; and
(b) shall be published in the *Canada Gazette* within 23 days after it is made.

Deeming

(5) For the purpose of any provision of this Act other than this section, any reference to regulations made under this Act is deemed to include interim orders, and any reference to a regulation made under a specified provision of this Act is deemed to include a reference to the portion of an interim order containing any provision that may be contained in a regulation made under the specified provision.

Tabling of order

(6) A copy of each interim order must be tabled in each House of Parliament within 15 days after it is made.

House not sitting

(7) In order to comply with subsection (6), the interim order may be sent to the Clerk of the House if the House is not sitting.

Offences and Punishment

Contravention of Act and regulations

31. Subject to section 31.1 every person who contravenes any of the provisions of this Act or of the regulations made under this Part is guilty of an offence and liable

(a) on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months or to both and, for a subsequent offence, to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months, or to both; and
(b) on conviction on indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years or to both.

Offences relating to food

31.1 Every person who contravenes any provision of this Act or the regulations, as it relates to food, is guilty of an offence and liable

(a) on summary conviction, to a fine not exceeding $50,000 or to imprisonment for a term not exceeding six months or to both; or
(b) on conviction by indictment, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding three years or to both.

Limitation period

32. (1) A prosecution for a summary conviction offence under this Act may be instituted at any time within two years after the time the subject-matter of the prosecution becomes known to the Minister or, in the case of a contravention of a provision of the Act that relates to food, to the Minister of Agriculture and Agri-Food.

Minister's certificate

(2) A document purporting to have been issued by the Minister referred to in subsection (1), certifying the day on which the subject-matter of any prosecution became known to the Minister, is admissible in evidence without proof of the signature or official character of the person appearing to have signed the document and is evidence of the matters asserted in it.

Venue

33. A prosecution for a contravention of this Act or the regulations may be instituted, heard, tried or determined in the place in which the offence was committed or the subject-matter of the prosecution arose or in any place in which the accused is apprehended or happens to be.

Want of knowledge

34. (1) Subject to subsection (2), in a prosecution for the sale of any article in contravention of this Act, except Parts III and IV, or of the regulations made under this Part, if the accused proves to the satisfaction of the court or judge that

(a) the accused purchased the article from another person in packaged form and sold it in the same package and in the same condition the article was in at the time it was so purchased, and

(b) that the accused could not with reasonable diligence have ascertained that the sale of the article would be in contravention of this Act or the regulations,

the accused shall be acquitted.

Notice of reliance on want of knowledge

(2) Subsection (1) does not apply in any prosecution unless the accused, at least ten days before the day fixed for the trial, has given to the prosecutor notice in writing that the accused intends to avail himself of the provisions of subsection (1) and has disclosed to the prosecutor the name and address of the person from whom the accused purchased the article and the date of purchase.

Certificate of analyst

35. (1) Subject to this section, in any prosecution for an offence under section 31, a certificate purporting to be signed by an analyst and stating that an article, sample or substance has been submitted to, and analysed or examined by, the analyst and stating the results of the analysis or examination is admissible in evidence and, in the absence of evidence to the contrary, is proof of the statements contained in the certificate without proof of the signature or official character of the person appearing to have signed it.

Requiring attendance of analyst

(2) The party against whom a certificate of an analyst is produced pursuant to subsection (1) may, with leave of the court, require the attendance of the analyst for the purposes of cross-examination.

Notice of intention to produce certificate

(3) No certificate shall be admitted in evidence pursuant to subsection (1) unless, before the trial, the party intending to produce the certificate has given reasonable notice of that intention, together with a copy of the certificate, to the party against whom it is intended to be produced.

Proof of service

(4) For the purposes of this Act, service of any certificate referred to in subsection (1) may be proved by oral evidence given under oath by, or by the affidavit or solemn declaration of, the person claiming to have served it.

Attendance for examination

(5) Notwithstanding subsection (4), the court may require the person who appears to have signed an affidavit or solemn declaration referred to in that subsection to appear before it for examination or cross-examination in respect of the issue of proof of service.

Proof as to manufacturer or packager

36. (1) In a prosecution for a contravention of this Act or of the regulations made under this Part, proof that a package containing any article to which this Act or the regulations apply bore a name or address purporting to be the name or address of the person by whom it was manufactured or packaged is, in the absence of evidence to the contrary, proof that the article was manufactured or packaged, as the case may be, by the person whose name or address appeared on the package.

Offence by employee or agent

(2) In a prosecution for a contravention described in subsection (1), it is sufficient proof of the offence to establish that it was committed by an employee or agent of the accused whether or not the employee or agent is identified or has been prosecuted for the offence.

Certified copies and extracts

(3) In a prosecution for a contravention described in subsection (1), a copy of a record or an extract therefrom certified to be a true copy by the inspector who made it pursuant to paragraph 23(1)(c) is admissible in evidence and is, in the absence of evidence to the contrary, proof of its contents.

Where accused had adulterating substances

(4) Where a person is prosecuted under this Part for having manufactured an adulterated food or drug for sale, and it is established that the person had in his possession or on his premises any substance the addition of which to that food or drug has been declared by regulation to cause the adulteration of the food or drug, the onus of proving that the food or drug was not adulterated by the addition of that substance lies on the accused.

Exports

Conditions under which exports exempt

37. (1) This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export" or "Exportation" and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.

Exception — General Council Decision

(2) Despite subsection (1), this Act applies in respect of any drug or device to be manufactured for the purpose of being exported in accordance with the General Council Decision, as defined in subsection 30(6), and the requirements of the Act and the regulations apply to the drug or device as though it were a drug or device to be manufactured and sold for consumption in Canada, unless the regulations provide otherwise.

PART III

Controlled Drugs

Repealed May 14, 1997.

PART IV

Restricted Drugs

Repealed May 14, 1997.

SCHEDULE A

(Section 3)

Alcoholism
Alcoolisme

21-10-99 | Alopecia (except hereditary androgenetic alopecia)
Alopécie (sauf l'alopécie androgénogénétique)

Anxiety state
États d'angoisse

Appendicitis
Appendicite

Arteriosclerosis
Artériosclérose

Arthritis
Arthrite

19-10-89 | Asthma
Asthme

Bladder disease
Vessie (maladies)

Cancer
Cancer

Convulsions
Convulsions

Depression
Dépression

Diabetes
Diabète

Disease of the prostate
Prostate (maladies)

Disorder of menstrual flow
Troubles du flot menstruel

Dysentery
Dysenterie

Edematous state
Oedème

Epilepsy
Épilepsie

Gall Bladder disease
Vésicule biliaire (maladies)

Gangrene
Gangrène

Glaucoma
Glaucome

Gout
Goutte

Heart disease
Coeur (maladies)

Hernia
Hernie

Hypertension
Hypertension

Hypotension
Hypotension

Impetigo
Impétigo

Influenza } deleted from schedule A
Influenza } by P.C. 1990-2003 of 20-9-90

Kidney disease
Reins (maladies)

Leukemia
Leucémie

Liver disease (except hepatitis) } 21-10-99
Foie (maladies sauf l'hépatite)

Nausea and vomiting of pregnancy
Nausées et vomissements de la grossesse

Obesity
Obésité

Pleurisy
Pleurésie

Pneumonia } deleted from schedule A
Pneumonie } by P.C. 1992-641 of 02-4-92

Poliomyelitis } deleted from schedule A
Poliomyélite } by P.C. 1992-641 of 02-4-92

Rheumatic fever
Rhumatisme articulaire aigu

Scabies } deleted from schedule A
Gale } by P.C. 1988-770 of 28-4-88

Septicemia
Septicémie

Sexual impotence
Impuissance sexuelle

Tetanus } deleted from schedule A
Tétanos } by P.C. 1992-641 of 02-4-92

Thrombotic and Embolic disorders
Maladies thrombotiques et embolies

Thyroid disease
Glande thyroidienne (affections)

Tuberculosis } deleted from schedule A
Tuberculose } by P.C. 1992-641 of 02-4-92

Tumor
Tumeurs

Ulcer of the gastro-intestinal tract
Ulcères des voies gastro-intestinales

Vaginitis } deleted from schedule A
Vaginite } by P.C. 1994-545 of 14-4-94

Venereal disease
Maladies vénériennes

SCHEDULE B

(Section 10)

The most recent editions, including all errata, supplements, revisions and addenda, of the following standards:

23-1-96 |

Item	*Column I* *Name*	*Column II* *Abbreviation*
1.	European Pharmacopoeia	(Ph.Eur.)
2.	Pharmacopée française	(Ph.F.)
3.	Pharmacopoeia Internationalis	(Ph.I.)
4.	The British Pharmacopoeia	(B.P.)
5.	The Canadian Formulary	(C.F.)
6.	The National Formulary	(N.F.)
7.	The Pharmaceutical Codex: Principles and Practices of Pharmaceuticals	
8.	The United States Pharmacopoeia	(U.S.P.)

*(R) Minor correction

SCHEDULE C
(Section 12)

Drugs, other than radionuclides, sold or represented for use in the preparation of radiopharmaceuticals

Drogues, autres que les radionucléides, vendues pour être employées dans la préparation de produits pharmaceutiques radioactifs ou présentées comme pouvant servir à cette fin

Radiopharmaceuticals

Produits pharmaceutiques radioactifs

SCHEDULE D
(Section 12)

Allergenic substances used for the treatment or diagnosis of allergic or immunological diseases
Substances allergènes utilisées pour le traitement ou le diagnostic d'affections allergiques ou immunitaires
Anterior pituitary extracts
Extraits hypophysaires (lobe antérieur)
Aprotinin
Aprotinine
23-3-89 Blood and blood derivatives
Sang et dérivés du sang
Cholecystokinin
Cholécystokinine
Drugs obtained by recombinant DNA procedures
Drogues obtenues par des procédures de recombinaison de l'ADN
Drugs, other than antibiotics, prepared from micro-organisms
Drogues, sauf les antibiotiques, préparées à partir de micro-organismes
Glucagon
Glucagon
Gonadotrophins
Gonadotrophines
Human plasma collected by plasmapheresis
Plasma humain prélevé par plasmaphérèse
Immunizing agents
Agents immunisants
Insulin
Insuline
24-7-85 Interferon

9-12-97 Monoclonal antibodies, their conjugates and derivatives
Anticorps monoclonaux et leurs dérivés et conjugués
Secretin
Sécrétine
9-12-97 Sensitivity Discs and Sensitivity Tablets } Repealed from schedule D by P.C. 1997-1824 of 9-12-97
Disques et comprimés de sensibilité
Abroger de l'annexe D par la C.P. 1997-1824 du 9 décembre 1997
Snake Venom
Venin de serpent
Urokinase
Urokinase

SCHEDULE E
(Section 13)

SCHEDULE F
(Section 15)

SCHEDULE G

Repealed May 14, 1997.

SCHEDULE H

Repealed May 14, 1997

Made by Order in Council	
by P.C. 1954-1915 of 8th December, 1954,	Gazetted December 22, 1954.
as amended	
by P.C. 1955-328 of 8th March, 1955,	Gazetted March 23, 1955.
by P.C. 1955-1093 of 21st July, 1955,	Gazetted August 10, 1955.
by P.C. 1956-567 of 12th April, 1956,	Gazetted April 25, 1956.
by P.C. 1956-871 of 7th June, 1956,	Gazetted June 27, 1956.
by P.C. 1956-1054 of 12th July, 1956,	Gazetted July 25, 1956.
by P.C. 1956-1148 of 26th July, 1956,	Gazetted August 8, 1956.
by P.C. 1956-1347 of 6th September, 1956,	Gazetted September 26, 1956.
by P.C. 1956-1423 of 20th September, 1956,	Gazetted October 10, 1956.
by P.C. 1956-1921 of 28th December, 1956,	Gazetted January 9, 1957.
by P.C. 1957-242 of 21st February, 1957,	Gazetted March 13, 1957.
by P.C. 1957-423 of 28th March, 1957,	Gazetted April 10, 1957.
by P.C. 1957-860 of 20th June, 1957,	Gazetted July 10, 1957.
by P.C. 1957-1294 of 25th September, 1957,	Gazetted October 9, 1957.
by P.C. 1958-11 of 2nd January, 1958,	Gazetted January 22, 1958.
by P.C. 1958-657 of 9th May, 1958,	Gazetted May 28, 1958.
by P.C. 1958-1299 of 18th September, 1958,	Gazetted October 8, 1958.
by P.C. 1959-226 of 26th February, 1959,	Gazetted March 11, 1959.
by P.C. 1959-912 of 16th July, 1959,	Gazetted August 12, 1959.
by P.C. 1959-1450 of 12th November, 1959,	Gazetted November 25, 1959.
by P.C. 1959-1594 of 18th December, 1959,	Gazetted January 13, 1960.
by P.C. 1960-607 of 5th May, 1960,	Gazetted May 25, 1960.
by P.C. 1960-1141 of 17th August, 1960,	Gazetted September 14, 1960.
by P.C. 1960-1334 of 29th September, 1960,	Gazetted October 12, 1960.
by P.C. 1960-1674 of 8th December, 1960,	Gazetted December 28, 1960.
by P.C. 1960-1769 of 29th December, 1960,	Gazetted January 11, 1961.
by P.C. 1961-345 of 9th March, 1961,	Gazetted March 22, 1961.
by P.C. 1961-1061 of 24th July, 1961,	Gazetted August 9, 1961.
by P.C. 1961-1097 of 31st July, 1961,	Gazetted August 9, 1961.
by P.C. 1961-1132 of 9th August, 1961,	Gazetted August 23, 1961.
by P.C. 1961-1441 of 5th October, 1961,	Gazetted October 25, 1961.
by P.C. 1961-1832 of 21st December, 1961,	Gazetted January 10, 1962.
by P.C. 1962-687 of 12th May, 1962,	Gazetted May 23, 1962.
by P.C. 1962-1832 of 21st December, 1962,	Gazetted January 9, 1963.
by P.C. 1963-365 of 4th March, 1963,	Gazetted March 27, 1963.
by P.C. 1963-449 of 18th March, 1963,	Gazetted April 10, 1963.
by P.C. 1963-687 of 2nd May, 1963,	Gazetted May 22, 1963.
by P.C. 1963-1051 of 11th July, 1963,	Gazetted July 24, 1963.
by P.C. 1963-1119 of 25th July, 1963,	Gazetted August 14, 1963.
by P.C. 1963-1493 of 10th October, 1963,	Gazetted October 23, 1963.
by P.C. 1963-1642 of 7th November, 1963,	Gazetted November 27, 1963.
by P.C. 1964-319 of 28th February, 1964,	Gazetted March 25, 1964.
by P.C. 1964-887 of 18th June, 1964,	Gazetted July 8, 1964.
by P.C. 1964-1309 of 25th August, 1964,	Gazetted September 9, 1964.
by P.C. 1964-1355 of 3rd September, 1964,	Gazetted September 23, 1964.
by P.C. 1964-1856 of 4th December, 1964,	Gazetted December 23, 1964.
by P.C. 1965-550 of 25th March, 1965,	Gazetted April 14, 1965.
by P.C. 1965-783 of 29th April, 1965,	Gazetted May 12, 1965.
by P.C. 1965-887 of 13th May, 1965,	Gazetted May 26, 1965.
by P.C. 1965-1165 of 23rd June, 1965,	Gazetted July 14, 1965.
by P.C. 1965-1791 of 4th October, 1965,	Gazetted October 27, 1965.
by P.C. 1965-1892 of 25th October, 1965,	Gazetted November 10, 1965.
by P.C. 1965-2193 of 8th December, 1965,	Gazetted December 22, 1965.
by P.C. 1966-165 of 31st January, 1966,	Gazetted February 23, 1966.
by P.C. 1966-166 of 31st January, 1966,	Gazetted February 23, 1966.
by P.C. 1966-310 of 18th February, 1966,	Gazetted March 9, 1966.
by P.C. 1966-429 of 10th March, 1966,	Gazetted March 23, 1966.
by P.C. 1966-594 of 31st March, 1966,	Gazetted April 13, 1966.
by P.C. 1966-864 of 13th May, 1966,	Gazetted May 25, 1966.
by P.C. 1966-865 of 13th May, 1966,	Gazetted May 25, 1966.
by P.C. 1966-1008 of 2nd June, 1966,	Gazetted June 22, 1966.
by P.C. 1966-1316 of 14th July, 1966,	Gazetted July 27, 1966.

*(R) Minor correction

as amended

by P.C. 1966-1716 of 8th September, 1966,	Gazetted September 28, 1966.
by P.C. 1966-2118 of 10th November, 1966,	Gazetted November 23, 1966.
by P.C. 1966-2452 of 29th December, 1966,	Gazetted January 11, 1967.
by P.C. 1967-285 of 16th February, 1967,	Gazetted March 8, 1967.
by P.C. 1967-504 of 16th March, 1967,	Gazetted April 12, 1967.
by P.C. 1967-993 of 18th May, 1967,	Gazetted June 14, 1967.
by P.C. 1967-1209 of 15th June, 1967,	Gazetted June 28, 1967.
by P.C. 1967-1369 of 12th July, 1967,	Gazetted July 26, 1967.
by P.C. 1967-1561 of 9th August, 1967,	Gazetted August 23, 1967.
by P.C. 1967-1597 of 16th August, 1967,	Gazetted September 13, 1967.
by P.C. 1967-1635 of 23rd August, 1967,	Gazetted September 13, 1967.
by P.C. 1967-1857 of 28th September, 1967,	Gazetted October 11, 1967.
by P.C. 1967-2040 of 26th October, 1967,	Gazetted November 8, 1967.
by P.C. 1967-2191 of 23rd November, 1967,	Gazetted December 13, 1967.
by P.C. 1968-392 of 28th February, 1968,	Gazetted March 13, 1968.
by P.C. 1968-856 of 2nd May, 1968,	Gazetted May 22, 1968.
by P.C. 1968-902 of 8th May, 1968,	Gazetted May 22, 1968.
by P.C. 1968-943 of 15th May, 1968,	Gazetted June 12, 1968.
by P.C. 1968-1045 of 29th May, 1968,	Gazetted June 12, 1968.
by P.C. 1968-1245 of 28th June, 1968,	Gazetted July 24, 1968.
by P.C. 1968-1397 of 17th July, 1968,	Gazetted August 14, 1968.
by P.C. 1968-1736 of 5th September, 1968,	Gazetted September 25, 1968.
by P.C. 1968-1872 of 1st October, 1968,	Gazetted October 23, 1968.
by P.C. 1968-2022 of 29th October, 1968,	Gazetted November 13, 1968.
by P.C. 1968-2134 of 19th November, 1968,	Gazetted December 11, 1968.
by P.C. 1969-73 of 14th January, 1969,	Gazetted February 12, 1969.
by P.C. 1969-74 of 14th January, 1969,	Gazetted February 12, 1969.
by P.C. 1969-276 of 11th February, 1969,	Gazetted February 26, 1969.
by P.C. 1969-384 of 25th February, 1969,	Gazetted March 12, 1969.
by P.C. 1969-479 of 11th March, 1969,	Gazetted March 26, 1969.
by P.C. 1969-480 of 11th March, 1969,	Gazetted March 26, 1969.
by P.C. 1969-735 of 15th April, 1969,	Gazetted May 14, 1969.
by P.C. 1969-854 of 29th April, 1969,	Gazetted May 14, 1969.
by P.C. 1969-981 of 13th May, 1969,	Gazetted May 28, 1969.
by P.C. 1969-982 of 13th May, 1969,	Gazetted May 28, 1969.
by P.C. 1969-1613 of 13th August, 1969,	Gazetted August 27, 1969.
by P.C. 1969-1614 of 13th August, 1969,	Gazetted August 27, 1969.
by P.C. 1969-1683 of 27th August, 1969,	Gazetted September 10, 1969.
by P.C. 1969-1943 of 8th October, 1969,	Gazetted October 22, 1969.
by P.C. 1969-2020 of 21st October, 1969,	Gazetted November 12, 1969.
by P.C. 1969-2143 of 5th November, 1969,	Gazetted November 26, 1969.
by P.C. 1969-2212 of 19th November, 1969,	Gazetted December 10, 1969.
by P.C. 1969-2247 of 26th November, 1969,	Gazetted December 10, 1969.
by P.C. 1969-2248 of 26th November, 1969,	Gazetted December 10, 1969.
by P.C. 1969-2357 of 12th December, 1969,	Gazetted December 24, 1969.
by P.C. 1969-2378 of 17th December, 1969,	Gazetted January 14, 1970.
by P.C. 1970-14 of 14th January, 1970,	Gazetted January 28, 1970.
by P.C. 1970-36 of 14th January, 1970,	Gazetted January 28, 1970.
by P.C. 1970-37 of 14th January, 1970,	Gazetted January 28, 1970.
by P.C. 1970-170 of 27th January, 1970,	Gazetted February 11, 1970.
by P.C. 1970-272 of 10th February, 1970,	Gazetted February 25, 1970.
by P.C. 1970-435 of 10th March, 1970,	Gazetted March 25, 1970.
by P.C. 1970-645 of 14th April, 1970,	Gazetted May 13, 1970.
by P.C. 1970-804 of 5th May, 1970,	Gazetted May 27, 1970.
by P.C. 1970-865 of 12th May, 1970,	Gazetted May 27, 1970.
by P.C. 1970-880 of 19th May, 1970,	Gazetted June 10, 1970.
by P.C. 1970-1070 of 16th June, 1970,	Gazetted June 24, 1970.
by P.C. 1970-1314 of 22nd July, 1970,	Gazetted August 12, 1970.
by P.C. 1970-1455 of 19th August, 1970,	Gazetted September 9, 1970.

*(R) Minor correction

as amended	
by P.C. 1970-1456 of 19th August, 1970,	Gazetted September 9, 1970.
by P.C. 1970-1457 of 19th August, 1970,	Gazetted September 9, 1970.
by P.C. 1970-1548 of 9th September, 1970,	Gazetted September 23, 1970.
by P.C. 1970-1619 of 16th September, 1970,	Gazetted October 14, 1970.
by P.C. 1970-1909 of 3rd November, 1970,	Gazetted November 25, 1970.
by P.C. 1970-1981 of 10th November, 1970,	Gazetted November 25, 1970.
by P.C. 1971-59 of 12th January, 1971,	Gazetted January 27, 1971.
by P.C. 1971-85 of 19th January, 1971,	Gazetted February 10, 1971.
by P.C. 1971-240 of 9th February, 1971,	Gazetted February 24, 1971.
by P.C. 1971-356 of 23rd February, 1971,	Gazetted March 10, 1971.
by P.C. 1971-446 of 9th March, 1971,	Gazetted March 24, 1971.
by P.C. 1971-656 of 6th April, 1971,	Gazetted April 28, 1971.
by P.C. 1971-706 of 20th April, 1971,	Gazetted May 12, 1971.
by P.C. 1971-1002 of 25th May, 1971,	Gazetted June 9, 1971.
by P.C. 1971-1258 of 23rd June, 1971,	Gazetted July 14, 1971.
by P.C. 1971-1429 of 15th July, 1971,	Gazetted August 11, 1971.
by P.C. 1971-1827 of 1st September, 1971,	Gazetted September 22, 1971.
by P.C. 1971-1893 of 7th September, 1971,	Gazetted September 22, 1971.
by P.C. 1971-1894 of 7th September, 1971,	Gazetted September 22, 1971.
by P.C. 1971-1988 of 21st September, 1971,	Gazetted October 13, 1971.
by P.C. 1971-2092 of 5th October, 1971,	Gazetted October 27, 1971.
by P.C. 1971-2087 of 9th November, 1971,	Gazetted November 24, 1971.
by P.C. 1971-2538 of 16th November, 1971,	Gazetted December 8, 1971.
by P.C. 1971-2814 of 21st December, 1971,	Gazetted January 12, 1972.
by P.C. 1972-16 of 18th January 1972,	Gazetted February 9, 1972.
by P.C. 1972-115 of 27th January, 1972,	Gazetted February 9, 1972.
by P.C. 1972-217 of 10th February, 1972,	Gazetted March 8, 1972.
by P.C. 1972-669 of 12th April, 1972,	Gazetted April 26, 1972.
by P.C. 1972-670 of 12th April, 1972,	Gazetted April 26, 1972.
by P.C. 1972-854 of 2nd May, 1972,	Gazetted May 24, 1972.
by P.C. 1972-976 of 9th May, 1972,	Gazetted May 24, 1972.
by P.C. 1972-1105 of 24th May, 1972,	Gazetted June 14, 1972.
by P.C. 1972-1224 of 6th June, 1972,	Gazetted June 28, 1972.
by P.C. 1972-1794 of 24th August, 1972,	Gazetted September 13, 1972.
by P.C. 1972-1752 of 24th August, 1972,	Gazetted September 13, 1972.
by P.C. 1972-2145 of 14th September, 1972,	Gazetted October 11, 1972.
by P.C. 1972-2467 of 5th October, 1972,	Gazetted October 25, 1972.
by P.C. 1972-2736 of 30th November, 1972,	Gazetted December 27, 1972.
by P.C. 1972-2727 of 30th November, 1972,	Gazetted December 27, 1972.
by P.C. 1972-2968 of 12th December, 1972,	Gazetted January 10, 1973.
by P.C. 1972-3049 of 19th December, 1972,	Gazetted January 10, 1973.
by P.C. 1972-3074 of 21st December, 1972,	Gazetted January 10, 1973.
by P.C. 1973-227 of 30th January, 1973,	Gazetted February 14, 1973.
by P.C. 1973-414 of 20th February, 1973,	Gazetted March 14, 1973.
by P.C. 1973-415 of 20th February, 1973,	Gazetted March 14, 1973.
by P.C. 1973-468 of 27th February, 1973,	Gazetted March 14, 1973.
by P.C. 1973-742 of 27th March, 1973,	Gazetted April 11, 1973.
by P.C. 1973-743 of 27th March, 1973,	Gazetted April 11, 1973.
by P.C. 1973-711 of 27th March, 1973,	Gazetted April 11, 1973.
by P.C. 1973-1106 of 10th May, 1973,	Gazetted May 23, 1973.
by P.C. 1973-1512 of 12th June, 1973,	Gazetted June 27, 1973.
by P.C. 1973-1513 of 12th June, 1973,	Gazetted June 27, 1973.
by P.C. 1973-1514 of 12th June, 1973,	Gazetted June 27, 1973.
by P.C. 1973-1800 of 26th June, 1973,	Gazetted July 11, 1973.
by P.C. 1973-1982 of 10th July, 1973,	Gazetted July 25, 1973.
by P.C. 1973-2236 of 24th July, 1973,	Gazetted August 8, 1973.
by P.C. 1973-2758 of 18th September, 1973,	Gazetted October 10, 1973.
by P.C. 1973-2970 of 4th October, 1973,	Gazetted October 24, 1973.
by P.C. 1973-2971 of 4th October, 1973,	Gazetted October 24, 1973.
by P.C. 1973-3353 of 23rd October, 1973,	Gazetted November 7, 1973.

*(R) Minor correction

as amended	
by P.C. 1973-3326 of 23rd October, 1973,	Gazetted November 14, 1973.
by P.C. 1973-3587 of 13th November, 1973,	Gazetted November 28, 1973.
by P.C. 1973-3678 of 27th November, 1973,	Gazetted December 12, 1973.
by P.C. 1973-3679 of 27th November, 1973,	Gazetted December 12, 1973.
by P.C. 1973-3823 of 11th December, 1973,	Gazetted December 26, 1973.
by P.C. 1973-3824 of 11th December, 1973,	Gazetted December 26, 1973.
by P.C. 1974-33 of 8th January, 1974,	Gazetted January 23, 1974.
by P.C. 1974-168 of 23rd January, 1974,	Gazetted February 13, 1974.
by P.C. 1974-403 of 26th February, 1974,	Gazetted March 13, 1974.
by P.C. 1974-561 of 12th March, 1974,	Gazetted March 27, 1974.
by P.C. 1974-588 of 12th March, 1974,	Gazetted March 27, 1974.
by P.C. 1974-694 of 26th March, 1974,	Gazetted April 10, 1974.
by P.C. 1974-979 of 30th April, 1974,	Gazetted May 22, 1974.
by P.C. 1974-1233 of 30th May, 1974,	Gazetted June 12, 1974.
by P.C. 1974-1299 of 6th June, 1974,	Gazetted June 26, 1974.
by P.C. 1974-1378 of 13th June, 1974,	Gazetted June 26, 1974.
by P.C. 1974-1379 of 13th June, 1974,	Gazetted June 26, 1974.
by P.C. 1974-1571 of 16th July, 1974,	Gazetted August 14, 1974.
by P.C. 1974-1572 of 16th July, 1974,	Gazetted August 14, 1974.
by P.C. 1974-1933 of 28th August, 1974,	Gazetted September 11, 1974.
by P.C. 1974-1953 of 3rd September, 1974,	Gazetted September 25, 1974.
by P.C. 1974-2113 of 24th September, 1974,	Gazetted October 9, 1974.
by P.C. 1974-2255 of 8th October, 1974,	Gazetted October 23, 1974.
by P.C. 1974-2256 of 8th October, 1974,	Gazetted October 23, 1974.
by P.C. 1974-2296 of 22nd October, 1974,	Gazetted November 13, 1974.
by P.C. 1974-2385 of 29th October, 1974,	Gazetted November 13, 1974.
by P.C. 1974-2386 of 29th October, 1974,	Gazetted November 13, 1974.
by P.C. 1974-2430 of 5th November, 1974,	Gazetted November 27, 1974.
by P.C. 1974-2497 of 12th November, 1974,	Gazetted November 27, 1974.
by P.C. 1974-2728 of 10th December, 1974,	Gazetted December 26, 1974.
by P.C. 1974-2762 of 13th December, 1974,	Gazetted December 26, 1974.
by P.C. 1974-2826 of 17th December, 1974,	Gazetted January 8, 1975.
by P.C. 1975-7 of 16th January, 1975,	Gazetted February 12, 1975.
by P.C. 1975-8 of 16th January, 1975,	Gazetted February 12, 1975.
by P.C. 1975-135 of 23rd January, 1975,	Gazetted February 12, 1975.
by P.C. 1975-191 of 28th January, 1975,	Gazetted February 12, 1975.
by P.C. 1975-223 of 31st January, 1975,	Gazetted February 12, 1975.
by P.C. 1975-418 of 25th February, 1975,	Gazetted March 26, 1975.
by P.C. 1975-504 of 4th March, 1975,	Gazetted March 26, 1975.
by P.C. 1975-609 of 18th March, 1975,	Gazetted April 9, 1975.
by P.C. 1975-774 of 8th April 1975,	Gazetted April 23, 1975.
by P.C. 1975-775 of 8th April 1975,	Gazetted April 23, 1975.
by P.C. 1975-918 of 24th April 1975,	Gazetted May 14, 1975.
by P.C. 1975-919 of 24th April, 1975,	Gazetted May 14, 1975.
by P.C. 1975-1026 of 6th May, 1975,	Gazetted May 28, 1975.
by P.C. 1975-1087 of 13th May, 1975,	Gazetted May 28, 1975.
by P.C. 1975-1088 of 13th May, 1975,	Gazetted May 28, 1975.
by P.C. 1975-1449 of 24th June, 1975,	Gazetted July 9, 1975.
by P.C. 1975-1656 of 17th July, 1975,	Gazetted August 13, 1975.
by P.C. 1975-1657 of 17th July, 1975,	Gazetted August 13, 1975.
by P.C. 1975-1712 of 22nd July, 1975,	Gazetted August 13, 1975.
by P.C. 1975-1713 of 22nd July, 1975,	Gazetted August 13, 1975.
by P.C. 1975-1714 of 22nd July, 1975,	Gazetted August 13, 1975.
by P.C. 1975-1902 of 6th August, 1975,	Gazetted August 27, 1975.
by P.C. 1975-2101 of 11th September, 1975,	Gazetted September 24, 1975.
by P.C. 1975-2175 of 18th September, 1975,	Gazetted October 8, 1975.
by P.C. 1975-2272 of 25th September, 1975,	Gazetted October 8, 1975.
by P.C. 1975-2483 of 21st October, 1975,	Gazetted November 12, 1975.
by P.C. 1975-2596 of 7th November, 1975,	Gazetted November 26, 1975.
by P.C. 1975-2665 of 7th November, 1975,	Gazetted November 26, 1975.
by P.C. 1975-2755 of 25th November, 1975,	Gazetted December 10, 1975.
by P.C. 1975-2756 of 25th November, 1975,	Gazetted December 10, 1975.
by P.C. 1975-2872 of 11th December, 1975,	Gazetted December 24, 1975.
by P.C. 1975-2952 of 18th December, 1975,	Gazetted January 14, 1976.
by P.C. 1975-2953 of 18th December, 1975,	Gazetted January 14, 1976.
by P.C. 1976-1439 of 11th June, 1976,	Gazetted June 23, 1976.

*(R) Minor correction

as amended

by P.C. 1975-2756 of November 25, 1975,	Gazetted December 10, 1975.
by P.C. 1975-2872 of December 11, 1975,	Gazetted December 24, 1975.
by P.C. 1975-2952 of December 18, 1975,	Gazetted January 14, 1976.
by P.C. 1975-2953 of December 18, 1975,	Gazetted January 14, 1976.
by P.C. 1976-1439 of June 11, 1976,	Gazetted June 23, 1976.
by P.C. 1976-1645 of June 29, 1976,	Gazetted July 14, 1976.
by P.C. 1976-2089 of August 25, 1976,	Gazetted September 8, 1976.
by P.C. 1976-2090 of August 25, 1976,	Gazetted September 8, 1976.
by P.C. 1976-2091 of August 25, 1976,	Gazetted September 8, 1976.
by P.C. 1976-2092 of August 25, 1976,	Gazetted September 8, 1976.
by P.C. 1976-2093 of August 25, 1976,	Gazetted September 8, 1976.
by P.C. 1976-2781 of November 10, 1976,	Gazetted November 24, 1976.
by P.C. 1976-2782 of November 10, 1976,	Gazetted November 24, 1976.
by P.C. 1976-2783 of November 10, 1976,	Gazetted November 24, 1976.
by P.C. 1976-2784 of November 10, 1976,	Gazetted November 24, 1976.
by P.C. 1976-2942 of November 25, 1976,	Gazetted December 8, 1976.
by P.C. 1977-68 of January 20, 1977,	Gazetted February 9, 1977.
by P.C. 1977-69 of January 20, 1977,	Gazetted February 9, 1977.
by P.C. 1977-201 of February 3, 1977,	Gazetted February 23, 1977.
by P.C. 1977-202 of February 3, 1977,	Gazetted February 23, 1977.
by P.C. 1977-203 of February 3, 1977,	Gazetted February 23, 1977.
by P.C. 1977-204 of February 3, 1977,	Gazetted February 23, 1977.
by P.C. 1977-205 of February 3, 1977,	Gazetted February 23, 1977.
by P.C. 1977-368 of February 24, 1977,	Gazetted March 9, 1977.
by P.C. 1977-789 of March 24, 1977,	Gazetted April 13, 1977.
by P.C. 1977-1017 of April 5, 1977,	Gazetted April 27, 1977.
by P.C. 1977-1159 of April 28, 1977,	Gazetted May 11, 1977.
by P.C. 1977-1160 of April 28, 1977,	Gazetted May 11, 1977.
by P.C. 1977-1161 of April 28, 1977,	Gazetted May 11, 1977.
by P.C. 1977-1162 of April 28, 1977,	Gazetted May 11, 1977.
by P.C. 1977-1163 of April 28, 1977,	Gazetted May 11, 1977.
by P.C. 1977-1164 of April 28, 1977,	Gazetted May 11, 1977.
by P.C. 1977-1165 of April 28, 1977,	Gazetted May 11, 1977.
by P.C. 1977-1214 of May 5, 1977,	Gazetted May 25, 1977.
by P.C. 1977-1470 of May 26, 1977,	Gazetted June 8, 1977.
by P.C. 1977-1471 of May 26, 1977,	Gazetted June 8, 1977.
by P.C. 1977-2011 of July 14, 1977,	Gazetted August 10, 1977.
by P.C. 1977-2321 of August 10, 1977,	Gazetted August 24, 1977.
by P.C. 1977-2322 of August 10, 1977,	Gazetted August 24, 1977.
by P.C. 1977-2549 of September 15, 1977,	Gazetted September 28, 1977.
by P.C. 1977-2550 of September 15, 1977,	Gazetted September 28, 1977.
by P.C. 1977-2431 of August 31, 1977,	Gazetted September 28, 1977.
by P.C. 1977-2551 of September 15, 1977,	Gazetted October 12, 1977.
by P.C. 1977-2872 of October 7, 1977,	Gazetted October 26, 1977.
by P.C. 1977-3054 of October 27, 1977,	Gazetted November 9, 1977.
by P.C. 1977-3249 of November 17, 1977,	Gazetted December 14, 1977.
by P.C. 1977-3250 of November 17, 1977,	Gazetted December 14, 1977.
by P.C. 1977-3251 of November 17, 1977,	Gazetted December 14, 1977.
by P.C. 1977-3252 of November 17, 1977,	Gazetted December 14, 1977.
by P.C. 1977-3253 of November 17, 1977,	Gazetted December 14, 1977.
by P.C. 1977-3254 of November 17, 1977,	Gazetted December 14, 1977.
by P.C. 1977-3279 of November 17, 1977,	Gazetted December 14, 1977.
by P.C. 1977-3383 of December 1, 1977,	Gazetted December 28, 1977.
by P.C. 1977-3384 of December 1, 1977,	Gazetted December 28, 1977.
by P.C. 1977-3519 of December 15, 1977,	Gazetted December 28, 1977.
by P.C. 1978-73 of January 12, 1978,	Gazetted January 25, 1978.
by P.C. 1978-74 of January 12, 1978,	Gazetted January 25, 1978.
by P.C. 1978-207 of January 26, 1978,	Gazetted February 8, 1978.
by P.C. 1978-635 of March 2, 1978,	Gazetted March 22, 1978.
by P.C. 1978-1404 of April 27, 1978,	Gazetted May 10, 1978.
by P.C. 1978-1405 of April 27, 1978,	Gazetted May 10, 1978.
by P.C. 1978-1406 of April 27, 1978,	Gazetted May 10, 1978.
by P.C. 1978-1407 of April 27, 1978,	Gazetted May 10, 1978.
by P.C. 1978-1408 of April 27, 1978,	Gazetted May 10, 1978.

*(R) Minor correction

as amended

by P.C. 1978-1515 of May 4, 1978,	Gazetted May 24, 1978.
by P.C. 1978-1516 of May 4, 1978,	Gazetted May 24, 1978.
by P.C. 1978-1517 of May 4, 1978,	Gazetted May 24, 1978.
by P.C. 1978-1520 of May 4, 1978,	Gazetted May 24, 1978.
by P.C. 1978-1682 of May 18, 1978,	Gazetted June 14, 1978.
by P.C. 1978-2022 of June 22, 1978,	Gazetted July 12, 1978.
by P.C. 1978-2528 of August 9, 1978,	Gazetted August 23, 1978.
by P.C. 1978-2529 of August 9, 1978,	Gazetted August 23, 1978.
by P.C. 1978-2530 of August 9, 1978,	Gazetted August 23, 1978.
by P.C. 1978-2531 of August 9, 1978,	Gazetted August 23, 1978.
by P.C. 1978-2574 of August 16, 1978,	Gazetted September 13, 1978.
by P.C. 1978-2575 of August 16, 1978,	Gazetted September 13, 1978.
by P.C. 1978-2733 of August 30, 1978,	Gazetted September 13, 1978.
by P.C. 1978-2786 of September 6, 1978,	Gazetted September 27, 1978.
by P.C. 1978-2847 of September 13, 1978,	Gazetted September 27, 1978.
by P.C. 1978-3211 of October 19, 1978,	Gazetted November 8, 1978.
by P.C. 1978-3212 of October 19, 1978,	Gazetted November 8, 1978.
by P.C. 1978-3482 of November 16, 1978,	Gazetted December 13, 1978.
by P.C. 1978-3483 of November 16, 1978,	Gazetted December 13, 1978.
by P.C. 1978-3484 of November 16, 1978,	Gazetted December 13, 1978.
by P.C. 1978-3485 of November 16, 1978,	Gazetted December 13, 1978.
by P.C. 1978-3761 of December 14, 1978,	Gazetted January 10, 1979.
by P.C. 1978-3806 of December 21, 1978,	Gazetted January 10, 1979.
by P.C. 1979-211 of February 1, 1979,	Gazetted February 28, 1979.
by P.C. 1979-590 of March 1, 1979,	Gazetted March 28, 1979.
by P.C. 1979-672 of March 8, 1979,	Gazetted March 28, 1979.
by P.C. 1979-673 of March 8, 1979,	Gazetted March 28, 1979.
by P.C. 1979-674 of March 8, 1979,	Gazetted March 28, 1979.
by P.C. 1979-675 of March 8, 1979,	Gazetted March 28, 1979.
by P.C. 1979-676 of March 8, 1979,	Gazetted March 28, 1979.
by P.C. 1979-850 of March 22, 1979,	Gazetted April 14, 1979.
by P.C. 1979-1231 of April 11, 1979,	Gazetted May 9, 1979.
by P.C. 1979-1797 of June 28, 1979,	Gazetted July 11, 1979.
by P.C. 1979-1849 of July 12, 1979,	Gazetted July 25, 1979.
by P.C. 1979-2277 of August 24, 1979,	Gazetted September 12, 1979.
by P.C. 1979-2450 of September 13, 1979,	Gazetted September 26, 1979.
by P.C. 1979-2451 of September 13, 1979,	Gazetted September 26, 1979.
by P.C. 1979-2452 of September 13, 1979,	Gazetted September 26, 1979.
by P.C. 1979-2453 of September 13, 1979,	Gazetted September 26, 1979.
by P.C. 1979-2454 of September 13, 1979,	Gazetted September 26, 1979.
by P.C. 1979-2455 of September 13, 1979,	Gazetted September 26, 1979.
by P.C. 1979-2456 of September 13, 1979,	Gazetted September 26, 1979.
by P.C. 1979-2457 of September 13, 1979,	Gazetted September 26, 1979.
by P.C. 1979-2830 of October 18, 1979,	Gazetted November 14, 1979.
by P.C. 1979-2831 of October 18, 1979,	Gazetted November 14, 1979.
by P.C. 1979-2832 of October 18, 1979,	Gazetted November 14, 1979.
by P.C. 1979-3184 of November 22, 1979,	Gazetted December 12, 1979.
by P.C. 1979-3467 of December 19, 1979,	Gazetted January 9, 1980.
by P.C. 1980-1021 of April 17, 1980,	Gazetted May 14, 1980.
by P.C. 1980-1133 of May 1, 1980,	Gazetted May 14, 1980.
by P.C. 1980-1134 of May 1, 1980,	Gazetted May 14, 1980.
by P.C. 1980-1432 of May 29, 1980,	Gazetted June 11, 1980.
by P.C. 1980-1732 of June 26, 1980,	Gazetted July 7, 1980.
by P.C. 1980-1733 of June 26, 1980,	Gazetted July 7, 1980.
by P.C. 1980-1734 of June 26, 1980,	Gazetted July 7, 1980.
by P.C. 1980-1849 of July 10, 1980,	Gazetted July 23, 1980.
by P.C. 1980-1850 of July 10, 1980,	Gazetted July 23, 1980.
by P.C. 1980-1851 of July 10, 1980,	Gazetted July 23, 1980.
by P.C. 1980-1852 of July 10, 1980,	Gazetted July 23, 1980.
by P.C. 1980-1977 of July 24, 1980,	Gazetted August 13, 1980.
by P.C. 1980-2077 of July 31, 1980,	Gazetted August 27, 1980.
by P.C. 1980-2078 of July 31, 1980,	Gazetted August 27, 1980.
by P.C. 1980-2455 of September 12, 1980,	Gazetted September 24, 1980.
by P.C. 1980-2623 of October 2, 1980,	Gazetted October 22, 1980.
by P.C. 1980-3468 of December 18, 1980,	Gazetted January 14, 1981.
by P.C. 1980-3469 of December 18, 1980,	Gazetted January 14, 1981.

*(R) Minor correction

as amended	
by P.C. 1980-3503 of December 18, 1980,	Gazetted January 14, 1981.
by P.C. 1981-43 of January 8, 1981,	Gazetted January 28, 1981.
by P.C. 1981-149 of January 22, 1981,	Gazetted February 11, 1981.
by P.C. 1981-150 of January 22, 1981,	Gazetted February 11, 1981.
by P.C. 1981-347 of February 13, 1981,	Gazetted February 25, 1981.
by P.C. 1981-503 of February 26, 1981,	Gazetted March 11, 1981.
by P.C. 1981-657 of March 12, 1981,	Gazetted March 25, 1981.
by P.C. 1981-741 of March 19, 1981,	Gazetted April 8, 1981.
by P.C. 1981-1123 of April 23, 1981,	Gazetted May 13, 1981.
by P.C. 1981-1124 of April 23, 1981,	Gazetted May 13, 1981.
by P.C. 1981-1125 of April 23, 1981,	Gazetted May 13, 1981.
by P.C. 1981-1189 of May 7, 1981,	Gazetted May 27, 1981.
by P.C. 1981-1190 of May 7, 1981,	Gazetted May 27, 1981.
by P.C. 1981-1650 of June 8, 1981,	Gazetted July 8, 1981.
by P.C. 1981-1879 of July 9, 1981,	Gazetted July 22, 1981.
by P.C. 1981-1880 of July 9, 1981,	Gazetted July 22, 1981.
by P.C. 1981-1922 of July 16, 1981,	Gazetted August 12, 1981.
by P.C. 1981-2049 of July 23, 1981,	Gazetted August 12, 1981.
by P.C. 1981-2050 of July 23, 1981,	Gazetted August 12, 1981.
by P.C. 1981-2094 of July 29, 1981,	Gazetted August 12, 1981.
by P.C. 1981-2647 of September 24, 1981,	Gazetted October 14, 1981.
by P.C. 1981-3207 of November 12, 1981,	Gazetted November 25, 1981.
by P.C. 1981-3208 of November 12, 1981,	Gazetted November 25, 1981.
by P.C. 1982-118 of January 14, 1982,	Gazetted January 27, 1982.
by P.C. 1982-120 of January 14, 1982,	Gazetted January 27, 1982.
by P.C. 1982-383 of April 1, 1982,	Gazetted April 14, 1982.
by P.C. 1982-406 of April 13, 1982,	Gazetted April 28, 1982.
by P.C. 1982-429 of April 23, 1982,	Gazetted May 12, 1982.
by P.C. 1982-524 of May 21, 1982,	Gazetted June 9, 1982.
by P.C. 1982-541 of May 28, 1982,	Gazetted June 9, 1982.
by P.C. 1982-566 of June 3, 1982,	Gazetted June 23, 1982.
by P.C. 1982-596 of June 10, 1982,	Gazetted June 23, 1982.
by P.C. 1982-2304 of July 29, 1982,	Gazetted August 11, 1982.
by P.C. 1982-2305 of July 29, 1982,	Gazetted August 11, 1982.
by P.C. 1982-2378 of August 5, 1982,	Gazetted August 25, 1982.
by P.C. 1982-2379 of August 5, 1982,	Gazetted August 25, 1982.
by P.C. 1982-3104 of October 7, 1982,	Gazetted October 27, 1982.
by P.C. 1982-3695 of December 2, 1982,	Gazetted December 22, 1982.
by P.C. 1982-3717 of December 2, 1982,	Gazetted December 22, 1982.
by P.C. 1983-863 of March 24, 1983,	Gazetted April 13, 1983.
by P.C. 1983-864 of March 24, 1983,	Gazetted April 13, 1983.
by P.C. 1983-1105 of April 14, 1983,	Gazetted April 27, 1983.
by P.C. 1983-1339 of May 5, 1983,	Gazetted May 5, 1983.
by P.C. 1983-2085 of July 7, 1983,	Gazetted July 27, 1983.
by P.C. 1983-2373 of July 27, 1983,	Gazetted August 10, 1983.
by P.C. 1983-3440 of November 3, 1983,	Gazetted November 23, 1983.
by P.C. 1983-3441 of November 3, 1983,	Gazetted November 23, 1983.
by P.C. 1983-3875 of December 8, 1983,	Gazetted December 28, 1983.
by P.C. 1983-3876 of December 8, 1983,	Gazetted December 28, 1983.
by P.C. 1983-4019 of December 15, 1983,	Gazetted January 11, 1984.
by P.C. 1984-337 of February 2, 1984,	Gazetted February 22, 1984.
by P.C. 1984-1069 of March 29, 1984,	Gazetted April 18, 1984.
by P.C. 1984-1236 of April 12, 1984,	Gazetted May 2, 1984.
by P.C. 1984-1237 of April 12, 1984,	Gazetted May 2, 1984.
by P.C. 1984-1238 of April 12, 1984,	Gazetted May 2, 1984.
by P.C. 1984-1239 of April 12, 1984,	Gazetted May 2, 1984.
by P.C. 1984-1379 of April 18, 1984,	Gazetted May 2, 1984.
by P.C. 1984-1977 of June 7, 1984,	Gazetted June 27, 1984.
by P.C. 1984-1978 of June 7, 1984,	Gazetted June 27, 1984.
by P.C. 1984-2153 of June 21, 1984,	Gazetted July 11, 1984.
by P.C. 1984-2505 of July 12, 1984,	Gazetted July 25, 1984.
by P.C. 1984-2591 of July 18, 1984,	Gazetted August 8, 1984.
by P.C. 1984-2654 of July 25, 1984,	Gazetted August 8, 1984.
by P.C. 1984-2790 of August 8, 1984,	Gazetted August 22, 1984.
by P.C. 1984-3152 of September 12, 1984,	Gazetted October 3, 1984.
by P.C. 1984-3326 of October 11, 1984,	Gazetted October 31, 1984.
by P.C. 1984-3682 of November 15, 1984,	Gazetted November 28, 1984.

*(R) Minor correction

as amended

by P.C. 1984-3797 of November 29, 1984,	Gazetted December 12, 1984.
by P.C. 1985-289 of January 31, 1985,	Gazetted February 20, 1985.
by P.C. 1985-290 of January 31, 1985,	Gazetted February 20, 1985.
by P.C. 1985-292 of January 31, 1985,	Gazetted February 20, 1985.
by P.C. 1985-478 of February 14, 1985,	Gazetted March 6, 1985.
by P.C. 1985-906 of March 21, 1985,	Gazetted April 3, 1985.
by P.C. 1985-1879 of June 12, 1985,	Gazetted June 26, 1985.
by P.C. 1985-1939 of June 13, 1985,	Gazetted June 26, 1985.
by P.C. 1985-1940 of June 13, 1985,	Gazetted June 26, 1985.
by P.C. 1985-2068 of June 27, 1985,	Gazetted July 10, 1985.
by P.C. 1985-2284 of July 24, 1985,	Gazetted August 7, 1985.
by P.C. 1985-2290 of July 24, 1985,	Gazetted August 7, 1985.
by P.C. 1985-2354 of July 24, 1985,	Gazetted August 7, 1985.
by P.C. 1985-2456 of August 7, 1985,	Gazetted August 21, 1985.
by P.C. 1985-2457 of August 7, 1985,	Gazetted August 21, 1985.
by P.C. 1985-2873 of September 26, 1985,	Gazetted October 16, 1985.
by P.C. 1985-3196 of October 24, 1985,	Gazetted November 13, 1985.
by P.C. 1985-3197 of October 24, 1985,	Gazetted November 13, 1985.
by P.C. 1986-49 of January 10, 1986,	Gazetted January 22, 1986.
by P.C. 1986-51 of January 10, 1986,	Gazetted January 22, 1986.
by P.C. 1986-56 of January 10, 1986,	Gazetted January 22, 1986.
by P.C. 1986-288 of January 30, 1986,	Gazetted February 19, 1986.
by P.C. 1986-498 of February 27, 1986,	Gazetted March 19, 1986.
by P.C. 1986-618 of March 13, 1986,	Gazetted April 2, 1986.
by P.C. 1986-619 of March 13, 1986,	Gazetted April 2, 1986.
by P.C. 1986-1199 of May 22, 1986,	Gazetted June 11, 1986.
by P.C. 1986-1258 of May 29, 1986,	Gazetted June 11, 1986.
by P.C. 1986-1259 of May 29, 1986,	Gazetted June 11, 1986.
by P.C. 1986-1467 of June 19, 1986,	Gazetted July 9, 1986.
by P.C. 1986-1844 of August 13, 1986,	Gazetted September 3, 1986.
by P.C. 1986-1859 of August 13, 1986,	Gazetted September 3, 1986.
by P.C. 1986-2075 of September 11, 1986,	Gazetted October 1, 1986.
by P.C. 1986-2076 of September 11, 1986,	Gazetted October 1, 1986.
by P.C. 1986-2257 of September 30, 1986,	Gazetted October 15, 1986.
by P.C. 1986-2325 of October 9, 1986,	Gazetted October 29, 1986.
by P.C. 1986-2642 of November 27, 1986,	Gazetted December 10, 1986.
by P.C. 1986-2703 of December 4, 1986,	Gazetted December 24, 1986.
by P.C. 1986-2751 of December 4, 1986,	Gazetted December 24, 1986.
by P.C. 1986-2842 of December 18, 1986,	Gazetted January 7, 1987.
by P.C. 1986-2853 of December 18, 1986,	Gazetted January 7, 1987.
by P.C. 1987-396 of March 5, 1987,	Gazetted March 18, 1987.
by P.C. 1987-825 of April 30, 1987,	Gazetted May 13, 1987.
by P.C. 1987-1175 of June 11, 1987,	Gazetted June 24, 1987.
by P.C. 1987-1253 of June 25, 1987,	Gazetted July 8, 1987.
by P.C. 1987-1452 of July 30, 1987,	Gazetted August 19, 1987.
by P.C. 1987-1476 of July 30, 1987,	Gazetted August 19, 1987.
by P.C. 1987-1601 of July 30, 1987,	Gazetted August 19, 1987.
by P.C. 1987-1665 of August 14, 1987,	Gazetted September 2, 1987.
by P.C. 1987-1728 of August 14, 1987,	Gazetted September 2, 1987.
by P.C. 1987-1938 of September 17, 1987,	Gazetted September 30, 1987.
by P.C. 1987-2202 of October 22, 1987,	Gazetted November 11, 1987.
by P.C. 1987-2253 of November 6, 1987,	Gazetted November 25, 1987.
by P.C. 1987-2356 of November 26, 1987,	Gazetted December 9, 1987.
by P.C. 1987-2464 of December 10, 1987,	Gazetted December 23, 1987.
by P.C. 1987-2641 of December 17, 1987,	Gazetted January 6, 1988.
by P.C. 1988-34 of January 14, 1988,	Gazetted February 3, 1988.
by P.C. 1988-41 of January 14, 1988,	Gazetted February 3, 1988.
by P.C. 1988-310 of February 25, 1988,	Gazetted March 16, 1988.
by P.C. 1988-454 of March 10, 1988,	Gazetted March 30, 1988.
by P.C. 1988-623 of March 17, 1988,	Gazetted March 30, 1988.
by P.C. 1988-810 of April 28, 1988,	Gazetted May 11, 1988.
by P.C. 1988-882 of May 12, 1988,	Gazetted May 25, 1988.
by P.C. 1988-946 of May 19, 1988,	Gazetted June 8, 1988.
by P.C. 1988-1160 of June 16, 1988,	Gazetted July 6, 1988.
by P.C. 1988-1248 of June 23, 1988,	Gazetted July 6, 1988.
by P.C. 1988-1328 of June 30, 1988,	Gazetted July 20, 1988.

*(R) Minor correction

as amended	
by P.C. 1988-1457 of July 21, 1988,	Gazetted August 3, 1988.
by P.C. 1988-1603 of August 11, 1988,	Gazetted August 31, 1988.
by P.C. 1988-1604 of August 11, 1988,	Gazetted August 31, 1988.
by P.C. 1988-1609 of August 11, 1988,	Gazetted August 31, 1988.
by P.C. 1988-2021 of September 15, 1988,	Gazetted September 28, 1988.
by P.C. 1988-2252 of September 29, 1988,	Gazetted October 12, 1988.
by P.C. 1988-2376 of October 27, 1988,	Gazetted November 9, 1988.
by P.C. 1988-2457 of October 31, 1988,	Gazetted November 23, 1988.
by P.C. 1988-2642 of December 7, 1988,	Gazetted December 21, 1988.
by P.C. 1988-2643 of December 7, 1988,	Gazetted December 21, 1988.
by P.C. 1988-2883 of December 30, 1988,	Gazetted January 6, 1989.
by P.C. 1989-313 of March 2, 1989,	Gazetted March 15, 1989.
by P.C. 1989-377 of March 9, 1989,	Gazetted March 29, 1989.
by P.C. 1989-470 of March 23, 1989,	Gazetted April 12, 1989.
by P.C. 1989-472 of March 23, 1989,	Gazetted April 12, 1989.
by P.C. 1989-474 of March 23, 1989,	Gazetted April 12, 1989.
by P.C. 1989-475 of March 23, 1989,	Gazetted April 12, 1989.
by P.C. 1989-476 of March 23, 1989,	Gazetted April 12, 1989.
by P.C. 1989-565 of April 6, 1989,	Gazetted April 26, 1989.
by P.C. 1989-567 of April 6, 1989,	Gazetted April 26, 1989.
by P.C. 1989-568 of April 6, 1989,	Gazetted April 26, 1989.
by P.C. 1989-719 of April 28, 1989,	Gazetted May 10, 1989.
by P.C. 1989-782 of May 4, 1989,	Gazetted May 24, 1989.
by P.C. 1989-783 of May 4, 1989,	Gazetted May 24, 1989.
by P.C. 1989-1138 of June 15, 1989,	Gazetted July 5, 1989.
by P.C. 1989-1412 of July 24, 1989,	Gazetted August 16, 1989.
by P.C. 1989-1583 of August 24, 1989,	Gazetted September 13, 1989.
by P.C. 1989-1584 of August 24, 1989,	Gazetted September 13, 1989.
by P.C. 1989-1784 of September 21, 1989,	Gazetted October 11, 1989.
by P.C. 1989-1785 of September 21, 1989,	Gazetted October 11, 1989.
by P.C. 1989-2101 of October 19, 1989,	Gazetted November 8, 1989.
by P.C. 1989-2303 of November 23, 1989,	Gazetted December 6, 1989.
by P.C. 1989-2310 of November 23, 1989,	Gazetted December 6, 1989.
by P.C. 1989-2382 of December 7, 1989,	Gazetted December 20, 1989.
by P.C. 1989-2466 of December 14, 1989,	Gazetted January 3, 1990.
by P.C. 1990-52 of January 18, 1990,	Gazetted January 18, 1990.
by P.C. 1990-212 of February 8, 1990,	Gazetted February 28, 1990.
by P.C. 1990-505 of March 15, 1990,	Gazetted March 28, 1990.
by P.C. 1990-506 of March 15, 1990,	Gazetted March 28, 1990.
by P.C. 1990-655 of April 5, 1990,	Gazetted April 25, 1990.
by P.C. 1990-656 of April 5, 1990,	Gazetted April 25, 1990.
by P.C. 1990-759 of April 26, 1990,	Gazetted May 9, 1990.
by P.C. 1990-802 of May 3, 1990,	Gazetted May 23, 1990.
by P.C. 1990-1067 of June 7, 1990,	Gazetted June 20, 1990.
by P.C. 1990-1518 of July 27, 1990,	Gazetted August 15, 1990.
by P.C. 1990-1532 of July 27, 1990,	Gazetted August 15, 1990.
by P.C. 1990-1648 of July 27, 1990,	Gazetted August 15, 1990.
by P.C. 1990-1816 of August 28, 1990,	Gazetted September 12, 1990.
by P.C. 1990-1817 of August 28, 1990,	Gazetted September 12, 1990.
by P.C. 1990-1818 of August 28, 1990,	Gazetted September 12, 1990.
by P.C. 1990-2064 of September 27, 1990,	Gazetted October 10, 1990.
by P.C. 1990-2496 of November 22, 1990,	Gazetted December 5, 1990.
by P.C. 1990-2554 of November 29, 1990,	Gazetted December 19, 1990.
by P.C. 1990-2870 of December 31, 1990,	Gazetted January 30, 1991.
by P.C. 1990-2871 of December 31, 1990,	Gazetted January 30, 1991.
by P.C. 1990-2872 of December 31, 1990,	Gazetted January 30, 1991.
by P.C. 1991-173 of January 31, 1991,	Gazetted February 13, 1991.
by P.C. 1991-229 of February 14, 1991,	Gazetted February 27, 1991.
by P.C. 1991-433 of March 7, 1991,	Gazetted March 27, 1991.
by P.C. 1991-463 of March 14, 1991,	Gazetted March 27, 1991.
by P.C. 1991-466 of March 14, 1991,	Gazetted March 27, 1991.
by P.C. 1991-636 of April 11, 1991,	Gazetted April 24, 1991.
by P.C. 1991-767 of April 25, 1991,	Gazetted May 8, 1991.
by P.C. 1991-1088 of June 13, 1991,	Gazetted July 3, 1991.
by P.C. 1991-1217 of July 10, 1991,	Gazetted July 31, 1991.
by P.C. 1991-1218 of July 10, 1991,	Gazetted July 31, 1991.

*(R) Minor correction

as amended	
by P.C. 1991-1434 of August 13, 1991,	Gazetted August 28, 1991.
by P.C. 1991-1627 of September 5, 1991,	Gazetted September 25, 1991.
by P.C. 1991-1628 of September 5, 1991,	Gazetted September 25, 1991.
by P.C. 1991-1634 of September 5, 1991,	Gazetted September 25, 1991.
by P.C. 1991-1735 of September 19, 1991,	Gazetted October 9, 1991.
by P.C. 1991-1738 of September 19, 1991,	Gazetted October 9, 1991.
by P.C. 1991-2345 of November 28, 1991,	Gazetted December 18, 1991.
by P.C. 1991-2402 of December 5, 1991,	Gazetted December 18, 1991.
by P.C. 1991-2460 of December 12, 1991,	Gazetted January 1, 1992.
by P.C. 1992-62 of January 23, 1992,	Gazetted February 12, 1992.
by P.C. 1992-63 of January 23, 1992,	Gazetted February 12, 1992.
by P.C. 1992-64 of January 23, 1992,	Gazetted February 12, 1992.
by P.C. 1992-75 of January 23, 1992,	Gazetted February 12, 1992.
by P.C. 1992-179 of February 6, 1992,	Gazetted February 26, 1992.
by P.C. 1992-180 of February 6, 1992,	Gazetted February 26, 1992.
by P.C. 1992-181 of February 6, 1992,	Gazetted February 26, 1992.
by P.C. 1992-182 of February 6, 1992,	Gazetted February 26, 1992.
by P.C. 1992-193 of February 6, 1992,	Gazetted February 26, 1992.
by P.C. 1992-283 of February 20, 1992,	Gazetted March 11, 1992.
by P.C. 1992-284 of February 20, 1992,	Gazetted March 11, 1992.
by P.C. 1992-638 of April 2, 1992,	Gazetted April 22, 1992.
by P.C. 1992-640 of April 2, 1992,	Gazetted April 22, 1992.
by P.C. 1992-768 of April 30, 1992,	Gazetted May 20, 1992.
by P.C. 1992-771 of April 30, 1992,	Gazetted May 20, 1992.
by P.C. 1992-772 of April 30, 1992,	Gazetted May 20, 1992.
by P.C. 1992-773 of April 30, 1992,	Gazetted May 20, 1992.
by P.C. 1992-1173 of June 4, 1992,	Gazetted June 17, 1992.
by P.C. 1992-1174 of June 4, 1992,	Gazetted June 17, 1992.
by P.C. 1992-1295 of June 18, 1992,	Gazetted July 1st, 1992.
by P.C. 1992-1309 of June 18, 1992,	Gazetted July 1st, 1992.
by P.C. 1992-1864 of August 27, 1992,	Gazetted September 9, 1992.
by P.C. 1992-2057 of September 17, 1992,	Gazetted October 7, 1992.
by P.C. 1992-2049 of September 17, 1992,	Gazetted October 7, 1992.
by P.C. 1992-2193 of October 5, 1992,	Gazetted October 21, 1992.
by P.C. 1992-2261 of October 19, 1992,	Gazetted November 18, 1992.
by P.C. 1992-2317 of November 19, 1992,	Gazetted December 2, 1992.
by P.C. 1992-2327 of November 19, 1992,	Gazetted December 2, 1992.
by P.C. 1992-2341 of November 19, 1992,	Gazetted December 2, 1992.
by P.C. 1992-2342 of November 19, 1992,	Gazetted December 2, 1992.
by P.C. 1992-2343 of November 19, 1992,	Gazetted December 2, 1992.
by P.C. 1992-2533 of December 10, 1992,	Gazetted December 30, 1992.
by P.C. 1992-2534 of December 10, 1992,	Gazetted December 30, 1992.
by P.C. 1992-2535 of December 10, 1992,	Gazetted December 30, 1992.
by P.C. 1993-75 of January 28, 1993,	Gazetted February 10, 1993.
by P.C. 1993-405 of March 9, 1993,	Gazetted March 24, 1993.
by P.C. 1993-535 of March 23, 1993,	Gazetted April 7, 1993.
by P.C. 1993-768 of April 20, 1993,	Gazetted May 5, 1993.
by P.C. 1993-892 of May 4, 1993,	Gazetted May 19, 1993.
by P.C. 1993-893 of May 4, 1993,	Gazetted May 19, 1993.
by P.C. 1993-940 of May 11, 1993,	Gazetted June 2, 1993.
by P.C. 1993-1030 of May 25, 1993,	Gazetted June 16, 1993.
by P.C. 1993-1031 of May 25, 1993,	Gazetted June 16, 1993.
by P.C. 1993-1032 of May 25, 1993,	Gazetted June 16, 1993.
by P.C. 1993-1033 of May 25, 1993,	Gazetted June 16, 1993.
by P.C. 1993-1038 of May 25, 1993,	Gazetted June 16, 1993.
by P.C. 1993-1621 of August 4, 1993,	Gazetted August 25, 1993.
by P.C. 1993-1625 of August 4, 1993,	Gazetted August 25, 1993.
by P.C. 1993-1683 of August 26, 1993,	Gazetted September 8, 1993.
by P.C. 1993-1693 of August 26, 1993,	Gazetted September 8, 1993.
by P.C. 1993-1802 of September 23, 1993,	Gazetted October 6, 1993.
by P.C. 1993-1803 of September 23, 1993,	Gazetted October 6, 1993.
by P.C. 1993-1804 of September 23, 1993,	Gazetted October 6, 1993.
by P.C. 1993-1805 of September 23, 1993,	Gazetted October 6, 1993.
by P.C. 1993-1812 of September 23, 1993,	Gazetted October 6, 1993.
by P.C. 1993-1813 of September 23, 1993,	Gazetted October 6, 1993.
by P.C. 1993-1814 of September 23, 1993,	Gazetted October 6, 1993.

*(R) Minor correction

as amended

by P.C. 1993-2103 of December 15, 1993,	Gazetted December 29, 1993.
by P.C. 1994-7 of January 13, 1994,	Gazetted January 26, 1994.
by P.C. 1994-8 of January 13, 1994,	Gazetted January 26, 1994.
by P.C. 1994-14 of January 13, 1994,	Gazetted January 26, 1994.
by P.C. 1994-15 of January 13, 1994,	Gazetted January 26, 1994.
by P.C. 1994-16 of January 13, 1994,	Gazetted January 26, 1994.
by P.C. 1994-17 of January 13, 1994,	Gazetted January 26, 1994.
by P.C. 1994-62 of January 13, 1994,	Gazetted January 26, 1994.
by P.C. 1994-140 of January 27, 1994,	Gazetted February 9, 1994.
by P.C. 1994-227 of February 10, 1994,	Gazetted February 23, 1994.
by P.C. 1994-263 of February 16, 1994,	Gazetted March 9, 1994.
by P.C. 1994-264 of February 16, 1994,	Gazetted March 9, 1994.
by P.C. 1994-265 of February 16, 1994,	Gazetted March 9, 1994.
by P.C. 1994-314 of February 24, 1994,	Gazetted March 9, 1994.
by P.C. 1994-362 of March 1, 1994,	Gazetted March 23, 1994.
by P.C. 1994-488 of March 24, 1994,	Gazetted April 6, 1994.
by P.C. 1994-544 of April 14, 1994,	Gazetted May 4, 1994.
by P.C. 1994-545 of April 14, 1994,	Gazetted May 4, 1994.
by P.C. 1994-546 of April 14, 1994,	Gazetted May 4, 1994.
by P.C. 1994-547 of April 14, 1994,	Gazetted May 4, 1994.
by P.C. 1994-664 of April 28, 1994,	Gazetted May 18, 1994.
by P.C. 1994-856 of May 26, 1994,	Gazetted June 15, 1994.
by P.C. 1994-864 of May 26, 1994,	Gazetted June 15, 1994.
by P.C. 1994-934 of June 2, 1994,	Gazetted June 15, 1994.
by P.C. 1994-941 of June 2, 1994,	Gazetted June 15, 1994.
by P.C. 1994-942 of June 2, 1994,	Gazetted June 15, 1994.
by P.C. 1994-943 of June 2, 1994,	Gazetted June 15, 1994.
by P.C. 1994-1061 of June 23, 1994,	Gazetted July 13, 1994.
by P.C. 1994-1063 of June 23, 1994,	Gazetted July 13, 1994.
by P.C. 1994-1064 of June 23, 1994,	Gazetted July 13, 1994.
by P.C. 1994-1065 of June 23, 1994,	Gazetted July 13, 1994.
by P.C. 1994-1080 of June 23, 1994,	Gazetted July 13, 1994.
by P.C. 1994-1353 of August 16, 1994,	Gazetted September 7, 1994.
by P.C. 1994-1358 of August 16, 1994,	Gazetted September 7, 1994.
by P.C. 1994-1367 of August 16, 1994,	Gazetted September 7, 1994.
by P.C. 1994-1368 of August 16, 1994,	Gazetted September 7, 1994.
by P.C. 1994-1369 of August 16, 1994,	Gazetted September 7, 1994.
by P.C. 1994-1651 of October 6, 1994,	Gazetted October 19, 1994.
by P.C. 1994-1657 of October 6, 1994,	Gazetted October 19, 1994.
by P.C. 1994-1820 of November 1, 1994,	Gazetted November 30, 1994.
by P.C. 1994-1869 of November 15, 1994,	Gazetted November 30, 1994.
by P.C. 1994-1880 of November 15, 1994,	Gazetted November 30, 1994.
by P.C. 1994-2068 of December 14, 1994,	Gazetted December 28, 1994.
by P.C. 1994-2069 of December 14, 1994,	Gazetted December 28, 1994.
by P.C. 1995-10 of January 11, 1995,	Gazetted January 25, 1995.
by P.C. 1995-11 of January 11, 1995,	Gazetted January 25, 1995.
by P.C. 1995-12 of January 11, 1995,	Gazetted January 25, 1995.
by P.C. 1995-18 of January 11, 1995,	Gazetted January 25, 1995.
by P.C. 1995-569 of April 4, 1995,	Gazetted April 19, 1995.
by P.C. 1995-580 of April 4, 1995,	Gazetted April 19, 1995.
by P.C. 1995-662 of April 26, 1995,	Gazetted May 17, 1995.
by P.C. 1995-664 of April 26, 1995,	Gazetted May 17, 1995.
by P.C. 1995-922 of June 13, 1995,	Gazetted June 28, 1995.
by P.C. 1995-1026 of June 23, 1995,	Gazetted July 12, 1995.
by P.C. 1995-1191 of July 26, 1995,	Gazetted August 9, 1995.
by P.C. 1995-1344 of August 16, 1995,	Gazetted September 6, 1995.
by P.C. 1995-1451 of August 30, 1995,	Gazetted September 20, 1995.
by P.C. 1995-1454 of August 30, 1995,	Gazetted September 20, 1995.
by P.C. 1995-1455 of August 30, 1995,	Gazetted September 20, 1995.
by P.C. 1995-1456 of August 30, 1995,	Gazetted September 20, 1995.

*(R) Minor correction

as amended

by P.C. 1995-1526 of September 13, 1995,	Gazetted October 4, 1995.
by P.C. 1995-1676 of October 3, 1995,	Gazetted October 18, 1995.
by P.C. 1995-1718 of October 17, 1995,	Gazetted November 1, 1995.
by P.C. 1995-1724 of October 17, 1995,	Gazetted November 1, 1995.
by P.C. 1995-1865 of November 7, 1995,	Gazetted November 29, 1995.
by P.C. 1995-1869 of November 7, 1995,	Gazetted November 29, 1995.
by P.C. 1995-1941 of November 23, 1995,	Gazetted December 13, 1995.
by P.C. 1995-1943 of November 23, 1995,	Gazetted December 13, 1995.
by P.C. 1995-1945 of November 23, 1995,	Gazetted December 13, 1995.
by P.C. 1995-2101 of December 13, 1995,	Gazetted December 27, 1995.
by P.C. 1996-15 of January 4, 1996,	Gazetted January 24, 1996.
by P.C. 1996-72 of January 23, 1996,	Gazetted February 7, 1996.
by P.C. 1996-81 of January 23, 1996,	Gazetted February 7, 1996.
by P.C. 1996-82 of January 23, 1996,	Gazetted February 7, 1996.
by P.C. 1996-347 of March 19, 1996,	Gazetted April 3, 1996.
by P.C. 1996-622 of April 30, 1996,	Gazetted May 15, 1996.
by P.C. 1996-623 of April 30, 1996,	Gazetted May 15, 1996.
by P.C. 1996-624 of April 30, 1996,	Gazetted May 15, 1996.
by P.C. 1996-683 of May 7, 1996,	Gazetted May 29, 1996.
by P.C. 1996-684 of May 7, 1996,	Gazetted May 29, 1996.
by P.C. 1996-709 of May 14, 1996,	Gazetted May 29, 1996.
by P.C. 1996-710 of May 14, 1996,	Gazetted May 29, 1996.
by P.C. 1996-711 of May 14, 1996,	Gazetted May 29, 1996.
by P.C. 1996-906 of June 20, 1996,	Gazetted July 10, 1996.
by P.C. 1996-1090 of July 10, 1996,	Gazetted July 24, 1996.
by P.C. 1996-1091 of July 10, 1996,	Gazetted July 24, 1996.
by P.C. 1996-1092 of July 10, 1996,	Gazetted July 24, 1996.
by P.C. 1996-1093 of July 10, 1996,	Gazetted July 24, 1996.
by P.C. 1996-1223 of August 7, 1996,	Gazetted August 21, 1996.
by P.C. 1996-1678 of November 5, 1996,	Gazetted November 27, 1996.
by P.C. 1996-1738 of November 19, 1996,	Gazetted December 11, 1996.
by P.C. 1996-1739 of November 19, 1996,	Gazetted December 11, 1996.
by P.C. 1996-1740 of November 19, 1996,	Gazetted December 11, 1996.
by P.C. 1996-1741 of November 19, 1996,	Gazetted December 11, 1996.
by P.C. 1996-1742 of November 19, 1996,	Gazetted December 11, 1996.
by P.C. 1996-1842 of December 5, 1996,	Gazetted December 25, 1996.
by P.C. 1996-1915 of December 19, 1996,	Gazetted January 8, 1997.
by P.C. 1996-1928 of December 19, 1996,	Gazetted January 8, 1997.
by P.C. 1996-1929 of Decembeer 19, 1996,	Gazetted January 8, 1997.
by P.C. 1997-20 of January 07, 1997,	Gazetted January 22, 1997.
by P.C. 1997-21 of January 07, 1997,	Gazetted January 22, 1997.
by P.C. 1997-27 of January 07, 1997,	Gazetted January 22, 1997.
by P.C. 1997-243 of February 18, 1997,	Gazetted March 5, 1997.
by P.C. 1997-286 of March 04, 1997,	Gazetted March 19, 1997.
by P.C. 1997-317 of March 11, 1997,	Gazetted April 2, 1997.
by P.C. 1997-381 of March 19, 1997,	Gazetted April 2, 1997.
by P.C. 1997-480 of April 08, 1997,	Gazetted April 30, 1997.
by P.C. 1997-481 of April 08, 1997,	Gazetted April 30, 1997.
by P.C. 1997-482 of April 08, 1997,	Gazetted April 30, 1997.
by P.C. 1997-483 of April 08, 1997,	Gazetted April 30, 1997.
by P.C. 1997-484 of April 08, 1997,	Gazetted April 30, 1997.
by P.C. 1997-485 of April 08, 1997,	Gazetted April 30, 1997.
by P.C. 1997-626 of April 22, 1997,	Gazetted May 14, 1997.
by P.C. 1997-845 of June 27, 1997,	Gazetted July 9, 1997.
by P.C. 1997-927 of July 03, 1997,	Gazetted July 23, 1997.
by P.C. 1997-1022 of July 25, 1997,	Gazetted August 20, 1997.
by P.C. 1997-1140 of August 28, 1997,	Gazetted September 17, 1997.
by P.C. 1997-1141 of August 28, 1997,	Gazetted September 17, 1997.
by P.C. 1997-1142 of August 28, 1997,	Gazetted September 17, 1997.
by P.C. 1997-1144 of August 28, 1997,	Gazetted September 17, 1997.
by P.C. 1997-1147 of August 28, 1997,	Gazetted September 17, 1997.
by P.C. 1997-1148 of August 28, 1997,	Gazetted September 17, 1997.
by P.C. 1997-1149 of August 28, 1997,	Gazetted September 17, 1997.

*(R) Minor correction

as amended

by P.C. 1997-1150 of August 28, 1997,	Gazetted September 17, 1997.
by P.C. 1997-1151 of August 28, 1997,	Gazetted September 17, 1997.
by P.C. 1997-1672 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1673 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1674 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1675 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1677 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1678 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1681 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1712 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1713 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1714 of November 20, 1997,	Gazetted December 10, 1997.
by P.C. 1997-1798 of December 04, 1997,	Gazetted December 24, 1997.
by P.C. 1997-1809 of December 04, 1997,	Gazetted December 24, 1997.
by P.C. 1997-1822 of December 09, 1997,	Gazetted December 24, 1997.
by P.C. 1997-1823 of December 09, 1997,	Gazetted December 24, 1997.
by P.C. 1997-1825 of December 09, 1997,	Gazetted December 24, 1997.
by P.C. 1997-1826 of December 09, 1997,	Gazetted December 24, 1997.
by P.C. 1997-1832 of December 09, 1997,	Gazetted December 24, 1997.
by P.C. 1997-1898 of December 17, 1997,	Gazetted January 07, 1998.
by P.C. 1997-1899 of December 17, 1997,	Gazetted January 07, 1998.
by P.C. 1998-54 of January 26, 1998,	Gazetted February 4, 1998.
by P.C. 1998-127 of February 5, 1998,	Gazetted February 18, 1998.
by P.C. 1998-783 of May 7, 1998,	Gazetted May 27, 1998.
by P.C. 1998-867 of May 14, 1998,	Gazetted May 27, 1998.
by P.C. 1998-868 of May 14, 1998,	Gazetted May 27, 1998.
by P.C. 1998-869 of May 14, 1998,	Gazetted May 27, 1998.
by P.C. 1998-870 of May 14, 1998,	Gazetted May 27, 1998.
by P.C. 1998-1461 of August 26, 1998,	Gazetted September 16, 1998.
by P.C. 1998-1498 of September 15, 1998,	Gazetted September 30, 1998.
by P.C. 1998-1574 of September 15, 1998,	Gazetted September 30, 1998.
by P.C. 1998-1599 of September 15, 1998,	Gazetted September 30, 1998.
by P.C. 1998-1929 of October 29, 1998,	Gazetted November 11, 1998.
by P.C. 1998-1980 of November 5, 1998,	Gazetted November 25, 1998.
by P.C. 1998-2142 of December 3, 1998,	Gazetted December 23, 1998.
by P.C. 1999-207 of February 11, 1999,	Gazetted March 3, 1999.
by P.C. 1999-208 of February 11, 1999,	Gazetted March 3, 1999.
by P.C. 1999-419 of March 11, 1999,	Gazetted March 12, 1999.
by P.C. 1999-1168 of June 23, 1999,	Gazetted July 7, 1999.
by P.C. 1999-1169 of June 23, 1999,	Gazetted July 7, 1999.
by P.C. 1999-1170 of June 23, 1999,	Gazetted July 7, 1999.
by P.C. 1999-1171 of June 23, 1999,	Gazetted July 7, 1999.
by P.C. 1999-1172 of June 23, 1999,	Gazetted July 7, 1999.
by P.C. 1999-1173 of June 23, 1999,	Gazetted July 7, 1999.
by P.C. 1999-1174 of June 23, 1999,	Gazetted July 7, 1999.
by P.C. 1999-1175 of June 23, 1999,	Gazetted July 7, 1999.
by P.C. 1999-1318 of July 28, 1999,	Gazetted August 18, 1999.
by P.C. 1999-1319 of July 28, 1999,	Gazetted August 18, 1999.
by P.C. 1999-1320 of July 28, 1999,	Gazetted August 18, 1999.
by P.C. 1999-1652 of September 29, 1999,	Gazetted October 3, 1999.
by P.C. 1999-1655 of September 29, 1999,	Gazetted October 3, 1999.
by P.C. 1999-1656 of September 29, 1999,	Gazetted October 3, 1999.
by P.C. 1999-1776 of October 6, 1999,	Gazetted October 27, 1999.
by P.C. 1999-1868 of October 21, 1999,	Gazetted November 10, 1999.
by P.C. 1999-1869 of October 21, 1999,	Gazetted November 10, 1999.
by P.C. 1999-1870 of October 21, 1999,	Gazetted November 10, 1999.
by P.C. 1999-1882 of October 21, 1999,	Gazetted November 10, 1999.
by P.C. 1999-1922 of October 28, 1999,	Gazetted November 10, 1999.
by P.C. 1999-1996 of November 4, 1999,	Gazetted November 24, 1999.
by P.C. 2000-88 of February 1, 2000,	Gazetted February 16, 2000.
by P.C. 2000-89 of February 1, 2000,	Gazetted February 16, 2000.
by P.C. 2000-124 of February 10, 2000,	Gazetted March 3, 2000.
by P.C. 2000-125 of February 10, 2000,	Gazetted March 3, 2000.

*(R) Minor correction

as amended

by P.C. 2000-405 of March 23, 2000,	Gazetted April 12, 2000.
by P.C. 2000-406 of March 23, 2000,	Gazetted April 12, 2000.
by P.C. 2000-413 of March 23, 2000,	Gazetted April 12, 2000.
by P.C. 2000-533 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-534 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-535 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-536 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-537 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-538 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-539 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-540 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-541 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-542 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-543 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-544 of April 13, 2000,	Gazetted April 26, 2000.
by P.C. 2000-728 of May 18, 2000,	Gazetted June 7, 2000.
by P.C. 2000-729 of May 18, 2000,	Gazetted June 7, 2000.
by P.C. 2000-730 of May 18, 2000,	Gazetted June 7, 2000.
by P.C. 2000-731 of May 18, 2000,	Gazetted June 7, 2000.
by P.C. 2000-732 of May 18, 2000,	Gazetted June 7, 2000.
by P.C. 2000-733 of May 18, 2000,	Gazetted June 7, 2000.
by P.C. 2000-829 of June 1, 2000,	Gazetted June 21, 2000.
by P.C. 2000-1100 of July 27, 2000,	Gazetted August 16, 2000.
by P.C. 2000-1141 of July 27, 2000,	Gazetted August 16, 2000.
by P.C. 2000-1350 of August 23, 2000,	Gazetted September 13, 2000.
by P.C. 2000-1423 of September 13, 2000,	Gazetted Spetember 27, 2000.
by P.C. 2000-1424 of September 13, 2000,	Gazetted September 27, 2000.
by P.C. 2000-1425 of September 13, 2000,	Gazetted September 27, 2000.
by P.C. 2000-1426 of September 13, 2000,	Gazetted September 27, 2000.
by P.C. 2000-1431 of September 13, 2000,	Gazetted September 27, 2000.
by P.C. 2000-1681 of November 13, 2000,	Gazetted December 6, 2000.
by P.C. 2000-1708 of November 30, 2000,	Gazetted December 20, 2000.
by P.C. 2000-1728 of November 30, 2000,	Gazetted December 20, 2000.
by P.C. 2001-154 of January 30, 2001,	Gazetted February 14, 2001.
by P.C. 2001-155 of January 30, 2001,	Gazetted February 14, 2001.
by P.C. 2001-156 of January 30, 2001,	Gazetted February 14, 2001.
by P.C. 2001-306 of March 1, 2001,	Gazetted March 14, 2001.
by P.C. 2001-307 of March 1, 2001,	Gazetted March 14, 2001.
by P.C. 2001-902 of May 17, 2001,	Gazetted June 6, 2001.
by P.C. 2001-1042 of June 7, 2001,	Gazetted June 20, 2001.
by P.C. 2001-1107 of June 14, 2001,	Gazetted July 4, 2001.
by P.C. 2001-1121 of June 14, 2001,	Gazetted July 4, 2001.
by P.C. 2001-1346 of August 1, 2001,	Gazetted August 15, 2001.
by P.C. 2001-1502 of August 28, 2001,	Gazetted September 12, 2001.
by P.C. 2001-1643 of September 20, 2001,	Gazetted October 10, 2001.
by P.C. 2001-1644 of September 20, 2001,	Gazetted October 10, 2001.
by P.C. 2001-1645 of September 20, 2001,	Gazetted October 10, 2001.
by P.C. 2001-1646 of September 20, 2001,	Gazetted October 10, 2001.
by P.C. 2001-1647 of September 20, 2001,	Gazetted October 10, 2001.
by P.C. 2001-1648 of September 20, 2001,	Gazetted October 10, 2001.
by P.C. 2001-1649 of September 20, 2001,	Gazetted October 10, 2001.
by P.C. 2001-1949 of October 25, 2001,	Gazetted November 7, 2001.
by P.C. 2001-1950 of October 25, 2001,	Gazetted November 7, 2001.
by P.C. 2001-1951 of October 25, 2001,	Gazetted November 7, 2001.
by P.C. 2001-1952 of October 25, 2001,	Gazetted November 7, 2001.
by P.C. 2001-1953 of October 25, 2001,	Gazetted November 7, 2001.
by P.C. 2001-1954 of October 25, 2001,	Gazetted November 7, 2001.
by P.C. 2001-1955 of October 25, 2001,	Gazetted November 7, 2001.
by P.C. 2001-1956 of October 25, 2001,	Gazetted November 7, 2001.
by P.C. 2001-1957 of October 25, 2001,	Gazetted November 7, 2001.
by P.C. 2001-2143 of November 22, 2001,	Gazetted December 5, 2001.
by P.C. 2001-2144 of November 22, 2001,	Gazetted December 5, 2001.
by P.C. 2001-2243 of December 6, 2001,	Gazetted December 19, 2001.
by P.C. 2001-2255 of December 6, 2001,	Gazetted December 19, 2001.

as amended

by P.C. 2002-86 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-87 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-91 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-92 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-93 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-94 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-792 of May 9, 2002,	Gazetted May 22, 2002.
by P.C. 2002-834 of May 23, 2002,	Gazetted June 5, 2002.
by P.C. 2002-896 of May 30, 2002,	Gazetted June 19, 2002.
by P.C. 2002-1581 of September 24, 2002,	Gazetted October 9, 2002.
by P.C. 2002-1710 of October 3, 2002,	Gazetted October 23, 2002.
by P.C. 2002-1711 of October 3, 2002,	Gazetted October 23, 2002.
by P.C. 2002-1794 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1795 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1796 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1797 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1798 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1799 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1800 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1801 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1802 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1897 of November 7, 2002,	Gazetted November 20, 2002.
by P.C. 2002-1898 of November 7, 2002,	Gazetted November 20, 2002.
by P.C. 2002-1899 of November 7, 2002,	Gazetted November 20, 2002.
by P.C. 2002-1900 of November 7, 2002,	Gazetted November 20, 2002.
by P.C. 2002-1901 of November 7, 2002,	Gazetted November 20, 2002.
by P.C. 2002-1954 of November 21, 2002,	Gazetted December 4, 2002.
by P.C. 2002-2170 of December 12, 2002,	Gazetted January 1, 2003.
by P.C. 2002-2200 of December 12, 2002,	Gazetted January 1, 2003.
by P.C. 2003-65 of January 30, 2003,	Gazetted February 12, 2003.
by P.C. 2003-67 of January 30, 2003,	Gazetted February 12, 2003.
by P.C. 2003-263 of February 27, 2003,	Gazetted March 12, 2003.
by P.C. 2003-465 of April 3, 2003,	Gazetted April 23, 2003.
by P.C. 2003-510 of April 10, 2003,	Gazetted April 23, 2003.
by P.C. 2003-598 of May 1, 2003,	Gazetted May 21, 2003.
by P.C. 2003-599 of May 1, 2003,	Gazetted May 21, 2003.
by P.C. 2003-600 of May 1, 2003,	Gazetted May 21, 2003.
by P.C. 2003-601 of May 1, 2003,	Gazetted May 21, 2003.
by P.C. 2003-602 of May 1, 2003,	Gazetted May 21, 2003.
by P.C. 2003-639 of May 8, 2003,	Gazetted May 21, 2003.
by P.C. 2003-640 of May 8, 2003,	Gazetted May 21, 2003.
by P.C. 2003-641 of May 8, 2003,	Gazetted May 21, 2003.
by P.C. 2003-686 of May 15, 2003,	Gazetted June 4, 2003.
by P.C. 2003-772 of May 29, 2003,	Gazetted June 18, 2003.
by P.C. 2003-847 of June 5, 2003,	Gazetted June 18, 2003.
by P.C. 2003-1002 of June 18, 2003,	Gazetted July 2, 2003.
by P.C. 2003-1047 of July 8, 2003,	Gazetted July 16, 2003.
by P.C. 2003-1057 of July 23, 2003,	Gazetted August 13, 2003.
by P.C. 2003-1208 of August 13, 2003,	Gazetted August 27, 2003.
by P.C. 2003-1496 of October 2, 2003,	Gazetted October 22, 2003.
by P.C. 2003-1498 of October 2, 2003,	Gazetted October 22, 2003.
by P.C. 2003-1500 of October 2, 2003,	Gazetted October 22, 2003.
by P.C. 2003-1829 of November 19, 2003,	Gazetted December 3, 2003.
by P.C. 2003-1830 of November 19, 2003,	Gazetted December 3, 2003.
by P.C. 2003-1831 of November 19, 2003,	Gazetted December 3, 2003.
by P.C. 2003-1909 of December 3, 2003,	Gazetted December 17, 2003.
by P.C. 2003-1991 of December 11, 2003,	Gazetted December 31, 2003.
by P.C. 2004-256 of March 23, 2004,	Gazetted April 7, 2004.
by P.C. 2004-257 of March 23, 2004,	Gazetted April 7, 2004.
by P.C. 2004-258 of March 23, 2004,	Gazetted April 7, 2004.

as amended

by P.C. 2004-259 of March 23, 2004,	Gazetted April 7, 2004.
by P.C. 2004-260 of March 23, 2004,	Gazetted April 7, 2004.
by P.C. 2004-261 of March 23, 2004,	Gazetted April 7, 2004.
by P.C. 2004-428 of April 22, 2004,	Gazetted May 5, 2004.
by P.C. 2004-538 of May 4, 2004,	Gazetted May 19, 2004.
by P.C. 2004-618 of May 11, 2004,	Gazetted June 2, 2004.
by P.C. 2004-1162 of October 12, 2004,	Gazetted November 3, 2004.
by P.C. 2004-1235 of October 26, 2004,	Gazetted November 17, 2004.
by P.C. 2004-1236 of October 26, 2004,	Gazetted November 17, 2004.
by P.C. 2004-1238 of October 26, 2004,	Gazetted November 17, 2004.
by P.C. 2004-1326 of November 16, 2004,	Gazetted December 1, 2004.
by P.C. 2004-1328 of November 16, 2004,	Gazetted December 1, 2004.
by P.C. 2004-1329 of November 16, 2004,	Gazetted December 1, 2004.
by P.C. 2004-1330 of November 16, 2004,	Gazetted December 1, 2004.
by P.C. 2004-1331 of November 16, 2004,	Gazetted December 1, 2004.
by P.C. 2004-1388 of November 23, 2004,	Gazetted December 15, 2004.
by P.C. 2004-1389 of November 23, 2004,	Gazetted December 15, 2004.
by P.C. 2004-1442 of November 29, 2004,	Gazetted December 15, 2004.
by P.C. 2005-388 of March 22, 2005,	Gazetted April 6, 2005.
by P.C. 2005-389 of March 22, 2005,	Gazetted April 6, 2005.
by P.C. 2005-390 of March 22, 2005,	Gazetted April 6, 2005.
by P.C. 2005-391 of March 22, 2005,	Gazetted April 6, 2005.
by P.C. 2005-488 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-489 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-490 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-491 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-492 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-493 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-494 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-495 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-496 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-497 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-498 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-499 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-500 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-501 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-502 of April 5, 2005,	Gazetted April 20, 2005.
by P.C. 2005-614 of April 19, 2005,	Gazetted May 4, 2005.
by P.C. 2005-858 of May 10, 2005,	Gazetted June 1, 2005.
by P.C. 2005-859 of May 10, 2005,	Gazetted June 1, 2005.
by P.C. 2005-860 of May 10, 2005,	Gazetted June 1, 2005.
by P.C. 2005-1053 of May 31, 2005,	Gazetted June 15, 2005.
by P.C. 2005-1275 of June 28, 2005,	Gazetted July 13, 2005.
by P.C. 2005-1518 of August 31, 2005,	Gazetted September 21, 2005.
by P.C. 2005-1521 of August 31, 2005,	Gazetted September 21, 2005.
by P.C. 2005-1723 of October 4, 2005,	Gazetted October 19, 2005.
by P.C. 2005-1724 of October 4, 2005,	Gazetted October 19, 2005.
by P.C. 2005-1825 of October 25, 2005,	Gazetted November 16, 2005.
by P.C. 2005-2219 of November 28, 2005,	Gazetted December 14, 2005.
by P.C. 2005-2220 of November 28, 2005,	Gazetted December 14, 2005.
by P.C. 2005-2221 of November 28, 2005,	Gazetted December 14, 2005.
by P.C. 2005-2222 of November 28, 2005,	Gazetted December 14, 2005.
by P.C. 2005-2223 of November 28, 2005,	Gazetted December 14, 2005.
by P.C. 2005-2316 of December 20, 2005,	Gazetted January 11, 2006.
by P.C. 2006-370 of May 11, 2006,	Gazetted May 31, 2006.
by P.C. 2006-545 of June 22, 2006,	Gazetted July 12, 2006.
by P.C. 2006-546 of June 22, 2006,	Gazetted July 12, 2006.
by P.C. 2006-804 of August 29, 2006,	Gazetted September 20, 2006.
by P.C. 2006-1004 of September 21, 2006,	Gazetted October 4, 2006.
by P.C. 2006-1005 of September 21, 2006,	Gazetted October 4, 2006.

as amended

by P.C. 2006-1006 of September 21, 2006,	Gazetted October 4, 2006.
by P.C. 2006-1007 of September 21, 2006,	Gazetted October 4, 2006.
by P.C. 2006-1008 of September 21, 2006,	Gazetted October 4, 2006.
by P.C. 2006-1076 of October 5, 2006,	Gazetted October 18, 2006.
by P.C. 2006-1105 of October 19, 2006,	Gazetted November 1, 2006

General

A.01.001. These regulations may be cited as the Food and Drug Regulations.

11-9-75 **A.01.002.** These regulations, where applicable, prescribe the standards of composition, strength, potency, purity, quality or other property of the article of food or drug to which they refer.

14-4-94 **A.01.003.** Revoked by P.C. 1994-547 of April 14, 1994.

Interpretation

A.01.010. In these regulations

21-9-89 "acceptable method" means a method of analysis or examination designated by the Director as acceptable for use in the administration of the Act and these Regulations; (*méthode acceptable*)

10-4-03 "Act" means the *Food and Drugs Act*, except in Parts G and J; (*Loi*)

10-4-03 "common-law partner", in relation to an individual, means a person who is cohabiting with the individual in a conjugal relationship, having so cohabited for a period of at least one year; (*conjoint de fait*)

"cubic centimetre" and its abbreviation "cc." shall be deemed to be interchangeable with the term "millilitre" and its abbreviation "ml.",

1-8-01 "Director" means the Assistant Deputy Minister, Health Products and Food Branch, of the Department of Health; (*Directeur*)

11-9-75 "inner label" means the label on or affixed to an immediate container of a food or drug,

15-9-77 "Lot number" means any combination of letters, figures, or both, by which any food or drug can be traced in manufacture and identified in distribution,

19-12-96 "manufacturer" or "distributor" means a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug; (*fabricant or distributeur*)

"official method" means a method of analysis or examination designated as such by the Director for use in the administration of the Act and these Regulations, and

15-9-77 "outer label" means the label on or affixed to the outside of a package of a food or drug,

13-9-00 "principal display panel" has the same meaning as in the *Consumer Packaging and Labelling Regulations*; (*espace principal*)

31-1-85 "security package" means a package having a security feature that provides reasonable assurance to consumers that the package has not been opened prior to purchase. (*emballage de securite*).

A.01.011. The Director shall, upon request, furnish copies of official methods.

A.01.012. The Director shall, upon request, indicate that a method is acceptable or otherwise upon its submission to him for a ruling.

11-9-75 **A.01.013.** Where a food, drug or vitamin has more than one name, whether proper or common, a reference in these Regulations to the food, drug or vitamin by any of its names is deemed to be a reference to the food, drug or vitamin by all of its names.

15-9-77

A.01.014. When a lot number is required by these Regulations to appear on any article, container, package or label it shall be preceded by one of the following designations:

(a) "Lot number";
(b) "Lot No.";
(c) "Lot"; or
(d) "(L)".

A.01.015. (1) Subject to subsection (2), any statement, information or declaration that is required by these Regulations to appear on the label of any drug shall be in either the French or the English language in addition to any other language.

31-1-85 (2) The adequate directions for use required to be shown on the inner and outer labels of a drug pursuant to subparagraph C.01.004(1)(c)(iii) shall be in both the French and English languages if the drug is available for sale without prescription in an open self-selection area.

15-9-77 **A.01.016.** All information required by these Regulations to appear on a label of a food or drug shall be
11-9-75

(a) clearly and prominently displayed on the label, and
23-6-71 (b) readily discernible to the purchaser or consumer under the customary conditions of purchase and use.

Analysts; Inspectors

A.01.020. Revoked by P.C. 1981-3208 of November 12, 1981.

A.01.021. Revoked by P.C. 1981-3208 of November 12, 1981.

11-9-75 **A.01.022.** An inspector shall perform the functions and duties and carry out the responsibilities in respect of foods
15-9-77 and drugs prescribed by the Act and these Regulations.

A.01.023. The authority of an inspector extends to and includes the whole of Canada.

29-10-92 **A.01.024.** The certificate of designation required pursuant to subsection 22(2) of the Act shall

(a) certify that the person named therein is an inspector for the purpose of the Act; and
(b) be signed by
9-3-76 (i) the Director and the person named in the certificate, in the case of an inspector on the staff of the Department, or
4-5-00 (ii) Repealed by P.C. 2000-184 of May 4, 2000.

1-10-68 **A.01.025.** Where authorized by a regulation made pursuant to the *Broadcasting Act*, inspectors shall act as representatives of the Canadian Radio-Television Commission for the purpose of enforcing the provisions of regulations made by the Canadian Radio-Television Commission concerning the advertising of any article to which the *Proprietary or Patent Medecine Act* or the *Food and Drugs Act* applies, or concerning recommendations for the prevention, treatment or cure of a disease or ailment.

A.01.026. An inspector may, for the proper administration of the Act or these Regulations, take photographs of

22-11-90 (a) any article that is referred to in subsection 23(2) of the Act;
(b) any place where, on reasonable grounds, he believes any article referred to in paragraph (a) is manufactured, prepared, preserved, packaged or stored; and
23-1-75 (c) anything that, on reasonable grounds, he believes is used or capable of being used for the manufacture, preparation, preservation, packaging or storing of any article referred to in paragraph (a).

Importations

15-9-77 **A.01.040.** Subject to section A.01.044, no person shall import into Canada for sale a food or drug the sale of which in Canada would constitute a violation of the Act or these Regulations.

15-9-77 **A.01.041.** An inspector may examine and take samples of any food or drug sought to be imported into Canada.

15-9-77 **A.01.042.** Where an inspector examines or takes a sample of a food or drug pursuant to section A.01.041, he may submit the food, drug or sample to an analyst for analysis or examination.

12-4-84 **A.01.043.** Where an inspector, upon examination of a food or drug or sample thereof or on receipt of a report of an analyst of the result of an analysis or examination of the food or drug or sample, is of the opinion that the sale of the food or drug in Canada would constitute a violation of the Act or these Regulations, the inspector shall so notify in writing the collector of customs concerned and the importer.

A.01.044. (1) Where a person seeks to import a food or drug into Canada for sale and the sale would constitute a violation of the Act or these Regulations, that person may, if the sale of the food or drug would be in conformity with the Act and these Regulations after its relabelling or modification, import it into Canada on condition that

(a) the person gives to an inspector notice of the proposed importation; and
27-7-00 (b) the food or drug will be relabelled or modified as may be necessary to enable its sale to be lawful in Canada.

27-7-00 (2) No person shall sell a food or drug that has been imported into Canada under subsection (1) unless the food or drug has been relabelled or modified within three months after the importation or within any longer period that may be specified by

(a) in the case of a drug, the Director; or
4-5-00 (b) in the case of food, the Director or the President of the Canadian Food Inspection Agency.

Exports

22-11-90 **A.01.045.** A certificate referred to in section 37 of the Act shall be signed and issued by the exporter in the form set out in Appendix III.

Sampling

22-11-90 **A.01.050.** When taking a sample of an article pursuant to paragraph 23(1)(a) of the Act, an inspector shall inform the owner thereof or the person from whom the sample is being obtained of the inspector's intention to submit the sample or a part thereof to an analyst for analysis or examination, and

(a) where, in the opinion of the inspector, division of the procured quantity would not interfere with analysis or examination
(i) divide the quantity into three parts,

*(R) Minor correction

(ii) identify the three parts as the owner's portion, the sample, and the duplicate sample and where only one part bears the label, that part shall be identified as the sample,

(iii) seal each part in such a manner that it cannot be opened without breaking the seal and

23-1-75 (iv) deliver the part identified as the owner's portion to the owner or the person from whom the sample was obtained and forward the sample and the duplicate sample to an analyst for analysis or examination, or

(b) where, in the opinion of the inspector, division of the procured quantity would interfere with analysis or examination

(i) identify the entire quantity as the sample,

(ii) seal the sample in such a manner that it cannot be opened without breaking the seal, and

(iii) forward the sample to an analyst for analysis or examination.

A.01.051. Where the owner or the person from whom the sample was obtained objects to the procedure followed by an inspector under A.01.050 at the time the sample was obtained, the inspector shall follow both procedures set out in that section if the owner or the person from whom the sample was obtained supplies him with a sufficient quantity of the article.

Tariff of Fees

A.01.060. The cost of analysing a sample other than for the purpose of the Act, for a department of the Government of Canada for the purpose of legal action is fifteen dollars.

15-9-77 ## Labelling of Food and Drugs in pressurized containers

A.01.060.1. In sections A.01.061 and A.01.062,

1-8-01 * "flame projection" means the ability of the pressurized contents of an aerosol container to ignite and the length of that ignition, when tested in accordance with official method DO-30, Determination of Flame Projection, dated October 15, 1981; (*projection de flamme*)

1-8-01 * "flashback" means that part of the flame projection that extends from its point of ignition back to the aerosol container when tested in accordance with official method DO-30, *Determination of Flame Projection*, dated October 15, 1981; (*retour de flamme*)

13-9-00 Repealed by P.C. 2000-1431 of September 13, 2000.

1-8-01 ***A.01.061.** (1) Subject to section A.01.063, in the case of a food or a drug packaged in a disposable metal container designed to release pressurized contents by use of a manually operated valve that forms an integral part of the container, the principal display panel of the inner and outer labels of the food or drug shall display, in accordance with sections 15 to 18 of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following information:

12-12-91 (a) the hazard symbol set out in column II of item 10 of Schedule II to those Regulations, accompanied by the signal word "CAUTION / ATTENTION"; and

(b) the primary hazard statement "CONTAINER MAY EXPLODE IF HEATED. / CE CONTENANT PEUT EXPLOSER S'IL EST CHAUFFÉ.".

1-8-01 * (2) Subject to section A.01.063, one panel of the inner and outer labels of a food or drug referred to in subsection (1) shall display, in the size required by paragraph 19(1)(b) of *the Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following additional hazard statement:

12-12-91 "Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store at temperatures over 50°C.
Contenu sous pression. Ne pas mettre dans l'eau chaude ni près des radiateurs, poêles ou autres sources de chaleur. Ne pas percer le contenant, ni le jeter au feu, ni le conserver à des températures dépassant 50°C."

(3) The requirements of subsections (1) and (2) do not apply where

15-9-77 (a) in relation to a drug, in the opinion of the Director, or

(b) in relation to a food, in the opinion of the Minister of Consumer and Corporate Affairs,

the design of the container, the materials used in its construction or the incorporation of a safety device eliminate the potential hazard therein.

* *Effective October 1, 2001*

1-8-01 | ***A.01.062.** (1) Subject to section A.01.063, if a food or drug is packaged in a container described in subsection A.01.061(1) and has a flame projection of a length set out in column I of any of items 1 to 3 of the table to this subsection or a flashback as set out in column I of item 4 of that table, as determined by official method DO-30, *Determination of Flame Projection*, dated October 15, 1981, the principal display panel of the inner and outer labels of the food or drug shall display, in accordance with sections 15 to 18 of *the Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following information:

12-12-91 | (a) the hazard symbol set out in column II of the same item;
(b) in both official languages, the signal word set out in column III of the same item; and
(c) in both official languages, the primary hazard statement set out in column IV of the same item.

TABLE

12-12-91

Item	Column I Flame Projection Length --- Flashback	Column II Hazard Symbol	Column III Signal Word	Column IV Primary Hazard Statement
1.	Less than 15 cm		Caution	Flammable
23-7-81 2.	15 cm or more but less than 45 cm		Warning	Flammable
3.	45 cm or more		Danger	Extremely Flammable
12-12-91 4.	Flashback		Danger	Extremely Flammable

1-8-01 | * (2) In addition to the requirements of subsection (1), one panel of the inner label and outer labels of a food or drug referred to in that subsection shall display, in the size required by paragraph 19(1)(b) of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following additional hazard statement:

12-12-91 | "Do not use in presence of open flame or spark.
Ne pas utiliser en présence d'une flamme nue ou d'étincelles."

A.01.063. (1) Where the labelled net contents of a container of a food or drug described in subsection A.01.061(1) or A.01.062(1) does not exceed 60 millilitres or 60 grams, the inner label may show only the information described in paragraph A.01.061(1)(a) or paragraphs A.01.062(1)(a) and (b), as the case may be.

23-7-81 | (2) Where the labelled net contents of a container of a food or drug described in subsection A.01.061(1) or A.01.062(1) exceeds 60 millilitres or 60 grams but does not exceed 120 millilitres or 120 grams, the inner label may show only the information described in subsection A.01.061(1) or subsection A.01.062(1), as the case may be.

* *Effective October 1, 2001*

12-12-91 (3) Where the labelled net quantity, in a container, of a food or drug referred to in subsection A.01.061(1) or A.01.062(1) is less than 30 mL or 30 g, the hazard symbol shall be of such size as to be capable of being circumscribed by a circle with a diameter of at least 6 mm.

23-7-81 (4) Where a container of a food or drug, described in subsection (1) or (2) is sold in a package, the outer label may show only the information described in subsection A.01.061(2) and, where applicable, subsection A.01.062(2).

11-5-93 **A.01.064.** Revoked by P.C. 1993-940 of May 11, 1993.

Security Packaging

A.01.065. (1) In this section, "drug for human use" means a drug that is intended for human use, whether the drug is
(a) a mouthwash;
(b) to be inhaled, ingested or inserted into the body; or
(c) for ophthalmic use.

19-11-92 (2) Subject to subsection (3), no person shall sell or import a drug for human use that is packaged and available to the general public in a self-service display, unless the drug is contained in a security package.

31-1-85 (3) Subsection (2) does not apply to lozenges.

(4) Subject to subsection (5), a statement or illustration that draws attention to the security feature of the security package referred to in subsection (2) shall be carried
(a) on the inner label of the package; and
19-11-92 (b) if the security feature is a part of the outer package, on the outer label.

(5) Subsection (4) does not apply if the security feature of a security package is self-evident and is an integral part of the immediate product container.

General

B.01.001. In this Part

"**agricultural chemical**" means any substance that
(a) is used or represented for use in or upon a food during production, storage or transport, or
25-11-76 (b) has been registered under *the Pest Control Products Act*
and the use of which results or may reasonably be expected to result in a residue for such substance or a derivative thereof in or upon foods, and includes any pesticide, plant growth regulator, fertilizer, adjuvant, carrier or ingredient used with such a substance, but does not include any
22-1-81 (c) food additives, other than those listed in the tables to Division 15,
(d) nutritive material that is used, recognized or commonly sold as an article or ingredient of food,
(e) vitamin, mineral nutrient or amino acid,
(f) spice, seasoning, flavouring preparation, essential oil, oleoresin or natural extractive,
(g) food packaging material or component thereof, or
(h) drug recommended for administration to animals that may be consumed as food; (*produit chimique agricole*)

* "**available display surface**", in respect of a prepackaged product, means
(a) the bottom of an ornamental container or the total surface area of both sides of a tag attached to the ornamental container, whichever is greater,
(b) the total surface area of both sides of a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, and
12-12-02 (c) the total surface area of any other package, excluding the bottom if the contents of the package leak out or are damaged when the package is turned over,
but does not include
(d) any area of a package on which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase,
(e) any part of a package that is intended to be destroyed when it is opened, other than a package of a food that is intended to be consumed by one person at a single eating occasion, or
(f) the area occupied by the universal product code; (*surface exposée disponible*)

12-3-74 "**close proximity**" means, with reference to the common name, immediately adjacent to the common name without any intervening printed, written or graphic matter; (*à proximité*)

"**common name**" means, with reference to a food,
(a) the name of the food printed in boldface type in these Regulations,
20-1-77 (b) the name prescribed by any other regulation, or
(c) if the name of the food is not so printed or prescribed, the name by which the food is generally known; (*nom usuel*)

"**component**" means an individual unit of food that is combined as an individual unit of food with one or more other individual units of food to form an ingredient; (*constituant*)

12-12-02 * "**daily value**" means
(a) in respect of a vitamin or mineral nutrient referred to in the definition "recommended daily intake", the recommended daily intake for that vitamin or mineral nutrient, and
(b) in respect of a nutrient referred to in the definition "reference standard", the reference standard for that nutrient; (*valeur quotidienne*)

12-3-74 "**durable life**" means the period, commencing on the day on which a prepackaged product is packaged for retail sale, during which the product, when it is stored under conditions appropriate to that product, will retain, without any appreciable deterioration, its normal wholesomeness, palatability, nutritional value and any other qualities claimed for it by the manufacturer; (*durée de conservation*)

"**durable life date**" means the date on which the durable life of a prepackaged product ends; (*date limite de conservation*)

* COMING INTO FORCE: *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

12-3-74 "**unstandardized food**" means any food for which a standard is not prescribed in this Part; (*aliment non normalisé*)

12-12-02 * "**weighted recommended nutrient intake**", in respect of a vitamin or mineral nutrient set out in column I of Table II to Division 1 of Part D or in column I of Table II to Division 2 of Part D, means the amount set out in column III; (*apport nutritionnel recommandé pondéré*)

"**yolk-replaced egg**" means a food that

(a) does not contain egg yolk but contains fluid, dried or frozen egg albumen or mixtures thereof,

20-1-77 (b) is intended as a substitute for whole egg, and

(c) meets the requirements of section B.22.032. (*oeuf à jaune substitué*)

12-12-02 ***B.01.001.1** (1) In this section, "fat" means all fatty acids expressed as triglycerides.

(2) The reference standard for a nutrient set out in column 1 of the table to this section is the amount set out in column 2.

TABLE

12-12-02 * **REFERENCE STANDARDS**

	Column 1	*Column 2*
Item	*Nutrient*	*Amount*
1.	Fat	65 g
2.	The sum of saturated fatty acids and *trans* fatty acids	20 g
3.	Cholesterol	300 mg
4.	Carbohydrate	300 g
5.	Fibre	25 g
6.	Sodium	2400 mg
7.	Potassium	3500 mg

18-10-79 **B.01.002.** Each provision in this Part in which the symbol [S] appears between the provision number and the name of the food described in that provision prescribes the standard of composition, strength, potency, purity, quality or other property of that food and a provision in which the symbol does not appear does not prescribe a standard for a food.

B.01.002A. For the purposes of this Part, a serving of stated size of a food shall be

31-10-88 (a) declared on the basis of the food as offered for sale;

(b) expressed

(i) in grams, where the net quantity of the food is declared on the label by weight, and

(ii) in millilitres, where the net quantity of the food is declared on the label by volume; and

(c) where the food is packaged in a container that could reasonably be construed as containing a single serving of the food, equal to the net quantity of the food.

* **Coming into force:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

***B.01.002A.** (1) For the purposes of this Part, a serving of stated size of a food shall be

(a) based on the food as offered for sale; and
(b) expressed
  (i) in grams, if
    (A) the net quantity of the food is declared on the label by weight or by count, or
    (B) the food is set out in column 1 of item 78, 149 or 150 of Schedule M, and
  (ii) in millilitres, if the net quantity of the food is declared on the label by volume, except in the case of a food referred to in clause (i) (B).

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(2) A serving of stated size shall be the net quantity of the food in the package if

(a) the quantity of food can reasonably be consumed by one person at a single eating occasion;
(b) the reference amount of the food is less than 100 g or 100 mL and the package contains less than 200% of that reference amount; or
(c) the reference amount of the food is 100 g or 100 mL or more and the package contains 150% or less of that reference amount.

B.01.003. The following foods shall carry a label when offered for sale:

12-3-74

(a) all prepackaged products other than
  (i) prepackaged confections, commonly known as one bite confections, that are sold individually, and
  (ii) prepackaged products consisting of fresh fruits or fresh vegetables that are packaged in a wrapper or confining band of less than ½ inch in width;
(b) meat and meat by-products that are barbecued, roasted or broiled on the retail premises; and
(c) poultry, poultry meat or poultry meat by-products that are barbecued, roasted or broiled on the retail premises;

13-5-75

(d) horse-meat or horse-meat by-product;
(e) any substance or mixture of substances for use as a food additive or food additive preparation; and
(f) flour and whole wheat flour that has been treated with gamma radiation from Cobalt 60 Source.

(2) Revoked by P.C. 1978-3806 of December 21, 1978.

*** COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

12-4-84 **B.01.004.** (1) All or part of the label referred to in section B.01.003 shall be applied

(a) in the case of a prepackaged product, to the container in which the prepackaged product is sold; and

(b) in the case of a food that is not a prepackaged product, to the food itself.

(2) The label shall be applied in such a manner that the container of the prepackaged product or the food, as the case may be, will bear the label at the time it is sold.

B.01.005. (1) Subject to subsections (2), (3) and (4), the information required to be shown on a label shall not be shown on the part of the label, if any, that is applied to the bottom of a food or container.

12-12-02 **B.01.005.** * (1) Subject to subsections (2) to (5), the information required to be shown on a label shall not be shown on that part of the label, if any, that is applied to the bottom of a food or container.

(2) The information required to be shown on a label may be shown on that part of the label, if any, that is applied to the bottom of a food or to the bottom of a container if such information is also shown in those parts of the label that are not applied to the bottom of the food or container.

12-3-74 (3) Notwithstanding subsection (2), where the container of a prepackaged product is an ornamental container and the label is applied to the bottom of the container, the information required to be shown may be shown on the label that is applied to the bottom of the container.

29-10-92 (4) Notwithstanding subsection (2), the information required by subparagraph B.01.007(1.1)(b)(i) or paragraph B.24.103(g) or B.25.057(1)(f) or (2)(f) may be shown on that part of the label that is applied to the bottom of the package if a clear indication of the location of the required information appears elsewhere on the label.

12-12-02 * (5) Notwithstanding subsection (2), the nutrition facts table may be shown on that part of the label that is applied to the bottom of the food or container if the available display surface includes the bottom.

B.01.006. (1) The common name of the food shall be shown on the principal display panel.

29-10-92 (2) Notwithstanding subsection (1), the common name of a fresh fruit or fresh vegetable that is prepackaged in such a manner that the fruit or vegetable is visible and identifiable in the package is not required to be shown on the label.

B.01.007. (1) In this section, "packaging date" means

(a) the date on which a food is placed for the first time in a package in which it will be offered for sale to a consumer; or

19-5-88 (b) the date on which a prepackaged product is weighed by a retailer in a package in which it will be offered for sale for the first time to a consumer.

(1.1) The following information shall be shown on any part of the label:

29-10-92 (a) the identity and principal place of business of the person by or for whom the food was manufactured or produced;

(b) where a prepackaged product having a durable life of 90 days or less is packaged at a place other than the retail premises from which it is to be sold,

(i) the durable life date, and

(ii) instructions for the proper storage of the prepackaged product if it requires storage conditions that differ from normal room temperature; and

19-5-88 (c) where a prepackaged product having a durable life of 90 days or less is packaged on the retail premises from which it is to be sold,

(i) the packaging date, and

(ii) the durable life of the food, except when the durable life appears on a poster next to the food.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

(1.2) The packaging date referred to in paragraph (1.1)(c) shall be shown in the form and manner prescribed for the durable life date by subsections (4) and (5) and the terms "best before" and "meilleur avant" on the label shall be replaced by the terms "packaged on" and "empaqueté le".

12-7-79 (2) Paragraph (1.1)(a) does not apply to fresh fruits or fresh vegetables that are prepackaged on retail premises in such a manner that the fruits or vegetables are visible and identifiable in the package.

(3) Paragraph (1.1)(b) and (c) do not apply to

(a) prepackaged products consisting of fresh fruits or fresh vegetables;
(b) prepackaged individual portions of food that are served by a restaurant or other commercial enterprise with meals or snacks;
(c) prepackaged individual servings of food that are prepared by a commissary and sold by automatic vending machines or mobile canteens; or
19-5-88 (d) prepackaged donuts.

(4) The durable life date shall be shown in the following manner:

13-5-75 (a) the words "best before" and "meilleur avant" shall be shown grouped together with the durable life date unless a clear explanation of the significance of the durable life date appears elsewhere on the label;
12-3-74 (b) where, for the sake of clarity, it is necessary to show the year in which the durable life date occurs, the year shall be shown first and shall be expressed by at least the last two numbers of the year;
(c) the month shall be shown in words after the year, if the year is shown, and may be abbreviated as prescribed by subsection (5); and
13-5-75 (d) the day of the month shall be shown after the month and shall be expressed in numbers.

(5) The month of the durable life date, when abbreviated, shall be abbreviated as follows and only one such abbreviation shall be used for the English language and the French language:

12-3-74

JA	for	JANUARY	JL	for	JULY
FE	for	FEBRUARY	AU	for	AUGUST
MR	for	MARCH	SE	for	SEPTEMBER
AL	for	APRIL	OC	for	OCTOBER
MA	for	MAY	NO	for	NOVEMBER
JN	for	JUNE	DE	for	DECEMBER

12-3-74 (6) Except as otherwise provided in these Regulations, no person shall use a durable life date marking system on the label of a prepackaged product or in advertising a prepackaged product other than the marking system set out in this section.

12-7-79 (7) Paragraph (1.1)(b) does not apply to prepackaged fresh yeast; if

20-1-77 (a) the date on which it is estimated that the product has lost its effectiveness is shown on the label in the form and manner prescribed for the durable life date by subsections (4) and (5); and
(b) the terms "best before" and "meilleur avant" are replaced by the terms "use by" and "employez avant".

12-3-74 **B.01.008.** (1) The following information shall be shown grouped together on any part of the label:

31-10-88 (a) any information required by these Regulations, other than the information required to appear on the principal display panel and the information required by section B.01.007 and B.01.310; and
12-12-02 * (a) any information required by these Regulations, other than the information required to appear on the principal display panel or the nutrition facts table and the information required by sections B.01.007, B.01.301, B.01.305, B.01.311, B.01.503, B.01.513 and B.01.601; and
(b) where a prepackaged product consists of more than one ingredient, a list of all ingredients, including, subject to section B.01.009, components, if any.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*
a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

(2) Paragraph (1)(b) does not apply to

29-10-92 (a) prepackaged products packaged from bulk on retail premises, except prepackaged products that are a mixture of nuts;
(b) prepackaged individual portions of food that are served by a restaurant or other commercial enterprise with meals or snacks;
(c) prepackaged individual servings of food that are prepared by a commissary and sold by automatic vending machines or mobile canteens;
(d) prepackaged meat and meat by-products that are barbecued, roasted or broiled on the retail premises;
(e) prepackaged poultry, poultry meat or poultry meat by-products that are barbecued, roasted or broiled on the retail premises;
23-3-93 (f) bourbon whisky and prepackaged products subject to compositional standards in Division 2; or
13-5-75 (g) prepackaged products subject to compositional standards in Division 19.

(3) Ingredients shall be shown in descending order of their proportion of the prepackaged product or as a percentage of the prepackaged product and the order or percentage shall be the order or percentage of the ingredients before they are combined to form the prepackaged product.

12-3-74 (4) Notwithstanding subsection (3), the following ingredients may be shown at the end of the list of ingredients in any order;

(a) spices, seasonings and herbs, except salt;
(b) natural and artificial flavours;
(c) flavour enhancers;
13-5-75 (d) food additives, except ingredients of food additive preparations or mixtures of substances for use as a food additive;
(e) vitamins;
(f) salts or derivatives of vitamins;
(g) mineral nutrients; and
12-3-74 (h) salts of mineral nutrients.

(5) Components shall be shown

(a) immediately after the ingredient of which they are components in such a manner as to indicate that they are components of that ingredient; and
(b) in descending order of their proportion of the ingredient.

29-10-92 (6) Notwithstanding paragraph (1)(b) and subsection (5), but subject to section B.01.009, where one or more components of an ingredient are required by these Regulations to be shown in the list of ingredients on the label of a prepackaged product, the ingredient that contains the components is not required to be shown in the list if all components of that ingredient are listed by their common names with the other ingredients of the product

(a) in descending order of their proportion of the product, or
(b) as a percentage of the product,

20-1-77 the order or percentage, as the case may be, being based
(c) in the case of components, on the total amount of each of the components before they are combined to form ingredients in the product, and
(d) in the case of ingredients, on the amount of each of the ingredients before they are combined to form the product.

(7) Notwithstanding paragraph (1)(b), wax coating compounds and their components are not required to be shown on the label of a prepackaged fresh fruit or fresh vegetable as an ingredient or component thereof.

29-10-92 (8) Notwithstanding paragraph (1)(b), sausage casings are not required to be shown on the label of prepackaged sausages as an ingredient or component thereof.

(9) Notwithstanding paragraph (1)(b), hydrogen, when used for hydrogenation purposes, is not required to be shown on the label of any prepackaged product as an ingredient or component thereof.

29-10-92 (10) Notwithstanding paragraph (1)(b), components of ingredients of a sandwich made with bread are not required to be shown in the list of ingredients on the label of the sandwich.

B.01.009. (1) Components of ingredients or of classes of ingredients set out in the following table are not required to be shown on a label:

TABLE

	Item	Ingredient
	1.	butter
	2.	margarine
	3.	shortening
	4.	lard
	5.	leaf lard
29-10-92	6.	monoglycerides
	7.	diglycerides
	8.	rice
	9.	starches or modified starches
	10.	breads subject to compositional standards in sections B.13.021 to B.13.029
	11.	flour
	12.	soy flour
	13.	graham flour
	14.	whole wheat flour
	15.	baking powder
	16.	milk subject to compositional standards in sections B.08.003 to B.08.027
	17.	chewing gumbase
	18.	sweetening agents subject to compositional standards in sections B.18.001 to B.18.018
20-5-97	19.	cocoa, low-fat cocoa
	20.	salt
	21.	vinegars subject to compositional standards in sections B.19.003 to B.19.007
23-3-93	22.	bourbon whisky and alcoholic beverages subject to compositional standards in sections B.02.001 to B.02.134
	23.	cheese for which a standard is prescribed in Division 8, if the total amount of cheese in a prepackaged product is less than 10 per cent of that packaged product
	24.	jams, marmalades and jellies subject to compositional standards in sections B.11.201 to B.11.241 when the total amount of those ingredients is less than 5 per cent of a prepackaged product
	25.	olives, pickles, relish and horse-radish when the total amount of those ingredients is less than 10 per cent of a prepackaged product
	26.	one or more vegetable or animal fats or oils for which a standard is prescribed in Division 9, and hydrogenated, modified or interesterified vegetable or animal fats or oils, if the total of those fats and oils as are contained in a prepackaged product is less than 15 per cent of that prepackaged product
	27.	prepared or preserved meat, fish, poultry meat, meat by-product or poultry by-product when the total amount of those ingredients is less than 10 per cent of a prepackaged product that consists of an unstandardized food
	28.	alimentary paste that does not contain egg in any form or any flour other than wheat flour
29-10-92	29.	bacterial culture
	30.	hydrolysed plant protein
	31.	carbonated water
	32.	whey, whey powder, concentrated whey, whey butter and whey butter oil
	33.	mould culture
	34.	chlorinated water and fluorinated water
	35.	gelatin
	36.	toasted wheat crumbs used in or as a binder, filler or breading in or on a food product

(2) Subject to subsection (3), where a preparation or mixture set out in the table to this subsection is added to a food, the ingredients and components of the preparation or mixture are not required to be shown on the label of that food.

TABLE

Item	*Preparation/Mixture*
1.	food colour preparations
2.	flavouring preparations
3.	artificial flavouring preparations
4.	spice mixtures
5.	seasoning or herb mixtures
6.	vitamin preparations
7.	mineral preparations
8.	food additive preparations
9.	rennet preparations
10.	food flavour-enhancer preparations
11.	compressed, dry, active or instant yeast preparations

29-10-92

(3) Where a preparation or mixture set out in the table to subsection (2) is added to a food, and the preparation or mixture contains one or more of the following ingredients or components, those ingredients or components shall be shown by their common names in the list of the ingredients of the food to which they are added as if they were ingredients of that food:

(a) salt;
(b) glutamic acid or its salts;
(c) hydrolysed plant protein;
(d) aspartame;
(e) potassium chloride; and
(f) any ingredient or component that performs a function in, or has any effect on, that food.

23-9-93

(4) Notwithstanding subsections (1) and (2) where any of the following components is contained in an ingredient set out in the tables to those subsections, that component shall be shown in the list of ingredients:

(a) peanut oil;
(b) hydrogenated or partially hydrogenated peanut oil; and
(c) modified peanut oil.

30-11-00

(5) Notwithstanding subsection B.01.008(10) and item 23 of the table to subsection (1), if lysozyme from egg white is added to a food described in section B.08.033 or B.08.034, the label of the food shall show "lysozyme from egg white" in the list of ingredients in the same manner that is required in subsection B.01.008(4) or (5), as applicable.

23-9-93

B.01.010. (1) In this section, «common name» includes a name set out in column II of the tables to subsection (3).

(2) An ingredient or component shall be shown in the list of ingredients by its common name.

(3) For the purposes of subsection (2),

(a) the ingredient or component set out in column I of an item of the following table shall be shown in the list of ingredients by the common name set out in column II of that item:

TABLE

		Column I	Column II
12-3-74	Item	Ingredient or Component	Common Name
	1.	any oil, fat or tallow described in section B.09.002 of Division 9, except lard, leaf or suet	the name of the meat from which the oil, fat or tallow is obtained plus oil, fat or tallow
23-9-93	2.	shortening or margarine containing fats or oils, except shortening or margarine containing coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter	shortening or margarine modified by vegetable oil or marine oil or be the common name of the vegetable, animal or marine oil or fat used
23-9-93	3.	Shortening, or margarine containing coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter	shortening or margarine modified by the common name of the vegetable oil or fat used
	4.	meat	the name of the meat
	5.	poultry meat	the name of the poultry
	6.	fish	the name of the fish
	7.	plant protein product	the name of the plant plus protein product
	8.	hydrolyzed plant protein produced by the enzymatic process	hydrolyzed plus the name of the plant plus protein
	9.	any protein isolate	the name of the source of the protein plus protein or the common name of the protein isolate
13-5-75	10.	any meat by-product described in section B.14.003, other than gelatin	the name of the meat plus by-product or the name of the meat plus the name of the meat by-product
	11.	any poultry meat by-product described in section B.22.003	the name of the poultry plus by-product or the name of the poultry plus the name of the poultry meat by-product
21-12-78	12.	any oil or fat referred to in section B.09.002 that has been hydrogenated or partially hydrogenated, including tallow, but not including lard	"hydrogenated" *plus the name of the meat from which the oil, fat or tallow is obtained, plus oil, fat or tallow*
20-1-77	13.	any oil or fat referred to in section B.09.002 of Division 9, including tallow, that has been modified by the complete or partial removal of a fatty acid	modified *plus the name of the meat from which the oil, fat or tallow is obtained, plus oil, fat or tallow*
23-9-93	14.	one or more vegetable fats or oils, except coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter, that have been hydrogenated or partially hydrogenated	hydrogenated vegetable oil *or* hydrogenated vegetable fat *or* hydrogenated *plus the specific name of the oil or fat*
23-9-93	15.	coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter that has been hydrogenated or partially hydrogenated	hydrogenated *plus the specific name of the oil or fat*
20-1-77	16.	one or more marine fats or oils that have been hydrogenated or partially hydrogenated	hydrogenated marine oil *or* hydrogenated marine fat *or* hydrogenated *plus the specific name of the oil or fat*
23-9-93	17.	one or more vegetable fats or oils, except coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter, that have been modified by the complete or partial removal of a fatty acid	modified vegetable oil *or* modified vegetable fat *or* modified *plus the specific name of the oil or fat*

*(R) Minor correction

TABLE -- (continued)

Item	Column I Ingredient or Component	Column II Common Name
18.	coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter that has been modified by the complete or partial removal of a fatty acid	modified *plus the specific name of the oil or fat*
19.	one or more marine fats or oils that have been modified by the complete or partial removal of a fatty acid	modified marine oil *or* modified *plus the specific name of the oil or fat*

23-9-93

29-10-92 (b) except when one of the ingredients or components set out in column I of the table to this paragraph is shown separately in the list of ingredients by its common name, all of the ingredients or components present in a food set out in column I of an item of that table may be shown collectively in the list of ingredients by the common name set out in column II of that item:

TABLE

13-5-75 Item	Column I Ingredient or Component	Column II Common Name
1. 23-9-93	one or more vegetable fats or oils, except coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter	vegetable oil or vegetable fat
2.	one or more marine fats or oils	marine oil
3. 20-11-97	one or more of the colours listed in Table III of Division 16, except annatto where used in accordance with paragraph B.14.031(*l*) or clause B.14.032(*d*)(xvi)(A) and except allura red and sunset yellow FCF where used in accordance with clauses B.14.32(*d*)(xvi)(B) and C), respectively	colour
4. 29-10-92	one or more substances prepared for their flavouring properties and produced from animal or vegetable raw materials or from food constituents derived solely from animal or vegetable raw materials	flavour
5.	one or more substances prepared for their flavouring properties and derived in whole or in part from components obtained by chemical synthesis	artificial flavour, imitation flavour or simulated flavour
6.	one or more spices, seasonings or herbs except salt	spices, seasonings or herbs
7.	any of the following in liquid, concentrated, dry, frozen or reconstituted form, namely, butter, buttermilk, butter oil, milk fat, cream, milk, partly skimmed milk, skim milk and any other component of milk the chemical composition of which has not been altered and that exists in the food in the same chemical state in which it is found in milk	milk ingredients
29-10-92 7.1	any of the following in liquid, concentrated, dry, frozen or reconstituted form, namely, calcium-reduced skim milk (obtained by the ion-exchange process), casein, caseinates, cultured milk products, milk serum proteins, ultrafiltered milk, whey, whey butter, whey cream and any other component of milk the chemical state of which has been altered from that in which it is found in milk	modified milk ingredients
7.2	one or more ingredients or components set out in item 7 combined with any one or more ingredients or components set out in item 7.1	modified milk ingredients

*(R) Minor correction

TABLE -- (continued)

	Item	Column I Ingredient or Component	Column II Common Name
20-1-77	8.	any combination of disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate and sodium acid pyrophosphate	sodium phosphate or sodium phosphates
	9.	one or more species of bacteria	bacterial culture
	10.	one or more species of mould	mold culture or mould culture
	11.	preparation containing rennin	rennet
5-4-05	12.	milk coagulating enzymes from *Aspergillus oryzae* RET-1 (pBoel777), *Endothia parasitica*, *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)) or *Mucor pusillus Lindt*	microbial enzyme
29-10-92	13.	one or more substances the function of which is to impart flavour and that are obtained solely from the plant or animal source after which the flavour is named	the name of the plant or animal source plus the word "flavour"
	14.	toasted wheat crumbs made by cooking a dough prepared with flour and water, which may be unleavened or chemically or yeast leavened, and which otherwise complies with the standard prescribed by section B.13.021 or B.13.022	toasted wheat crumbs
	15.	that portion of chewing gum, other than the coating, that does not impart sweetness, flavour or colour	gum base
	16.	sugar, liquid sugar, invert sugar or liquid invert sugar, singly or in combination	sugar
	17.	glucose syrups and isomerized glucose syrups, singly or in combination, where the fructose fraction does not exceed 60 per cent of the sweetener on a dry basis	glucose-fructose
29-10-92	18.	glucose syrups and isomerized glucose syrups, singly or in combination, where the fructose fraction exceeds 60 per cent of the sweetener on a dry basis	fructose syrup
	19.	sugar or glucose-fructose, singly or in combination	sugar/glucose-fructose
	20.	water to which carbon dioxide is added	carbonated water
	21.	one or more of the following food additives, namely, potassium bisulphite, potassium metabisulphite, sodium bisulphite, sodium metabisulphite, sodium sulphite, sodium dithionite, sulphurous acid and sulphur dioxide	sulphiting agents or sulphites
	22.	demineralized water or water otherwise treated to remove hardness or impurities, or fluoridated or chlorinated water	water
	23.	wine vinegar, spirit vinegar, alcohol vinegar, white vinegar, grain vinegar, malt vinegar, cider vinegar or apple vinegar, singly or in combination	vinegar

(4) Notwithstanding subsection (2) and subsections B.01.008 (5), where a food contains ingredients of the same class, those ingredients may be shown by a class name if

(a) they consist of more than one component and are not listed in the table to subsection B.01.009 (1); and

20-1-77 (b) their components are shown

(i) immediately after the class name of the ingredients of which they are components, in such a manner as to indicate that they are components of the ingredients, and

(ii) in descending order of their collective proportion of those ingredients.

*(R) Minor correction

B.01.011. (1) Where it is an acceptable manufacturing practice for a manufacturer to

(a) omit from his prepackaged product any food that is ordinarily an ingredient or component, or

12-3-74 (b) substitute in whole or in part in his prepackaged product any other food for a food that is ordinarily an ingredient or component, the list of ingredients for the 12 month period commencing from the time the label is applied to the prepackaged product may show as ingredients or components the foods that may be omitted and the foods that may be used as substitutes if

(c) all the foods that may be used as ingredients or components throughout the 12 month period are shown in the list of ingredients,

(d) it is clearly stated as part of the list of ingredients that the food shown as an ingredient or component may not be present or that another food may be substituted for a food shown as an ingredient or component, and

(e) the foods that may be omitted or substituted are grouped with the same class of foods that are used as ingredients or components and the foods within each such group are listed in descending order of the proportion in which they will probably be needed during the 12 month period.

(2) Where it is an acceptable manufacturing practice for a manufacturer to vary the proportions of ingredients or components of his prepackaged product, the list of ingredients for the 12 month period commencing from the time the label is applied to the prepackaged product may show the ingredients or components in the same proportions throughout the 12 month period if

(a) it is clearly stated as part of the list of ingredients that the proportions indicated are subject to change; and

(b) the ingredients or components are listed in descending order of the proportion in which they will probably be used during the 12 month period.

B.01.012. (1) In this section,

"local government unit" means a city, metropolitan government area, town, village, municipality or other area of local government but does not include any local government unit situated within a bilingual district established under the *Official Languages Act*; (*collectivité locale*)

"local food" means a food that is manufactured, processed, produced or packaged in a local government unit and sold only in

(a) the local government unit in which it is manufactured, processed or packaged,

(b) one or more local government units that are immediately adjacent to the one in which it is manufactured, processed, produced or packaged, or

12-3-74 (c) the local government unit in which it is manufactured, processed, produced or packaged and in one or more local government units that are immediately adjacent to the one in which it is manufactured, processed, produced or packaged; (*produit alimentaire local*)

"mother tongue" means the language first learned in childhood by persons in any area of Canada and still understood by them as ascertained by the decennial census taken immediately preceding the date on which the food referred to in subsection (3) is sold to the consumer; (*langue maternelle*)

"official languages" means the English language and the French language; (*langues officielles*)

"specialty food" means a food that

(a) has special religious significance and is used in religious ceremonies; or

(b) is an imported food

(i) that is not widely used by the population as a whole in Canada, and

(ii) for which there is no readily available substitute that is manufactured, processed, produced or packaged in Canada and that is generally accepted as being a comparable substitute; (*aliment spécial*)

"test market food" means a food that, prior to the date of the notice of intention respecting that food referred to in subsection (5), was not sold in Canada in that form and that differs substantially from any other food sold in Canada with respect to its composition, function, state or packaging form and includes a food referred to in section B.01.054, (*produit alimentaire d'essai*)

20-1-77 (2) Subject to subsections (9), (10) and (11), all information required by these Regulations to be shown on the label of a food shall be shown in both official languages.

(3) Subject to subsections (4) to (6), subsection (2) does not apply to a local food or test market food if

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(a) it is sold in a local government unit in which one of the official languages is the mother tongue of less than ten per cent of the total number of persons residing in the local government unit; and

(b) the information required by these Regulations to be shown on the label of a food is shown in the official language that is the mother tongue of at least ten per cent of the total number of persons residing in the local government unit.

(4) Where one of the official languages is the mother tongue of less than ten per cent of the total number of persons residing in a local government unit and the other official language is the mother tongue of less than ten per cent of the total number of persons residing in the same local government unit, subsection (3) does not apply.

4-5-00 (5) Subsection (3) does not apply to a test market food unless the person who intends to conduct the test marketing of the food has, six weeks prior to conducting the test marketing, filed with the President of the Canadian Food Inspection Agency a notice of intention in a form acceptable to the President.

(6) A test market food shall, for the purposes of subsection (3), cease to be a test market food upon the expiration of twelve cumulative months after the date on which it was first offered for sale as a test market food but any test market food that was acquired for resale by a person, other than the person who filed the notice of intention referred to in subsection (5), before the expiration of those twelve cumulative months, shall continue to be a test market food for the purposes of subsection (3) until it is sold.

21-12-78 (7) Subsection (2) does not apply to a specialty food if the information required by these Regulations to be shown on the label thereon is shown in one of the official languages.

(8) Where there are one or more surfaces on the label of a food that are of at least the same size and prominence as the principal display panel, the information required by these Regulations to be shown on the principal display panel may be shown in one official language if such information is shown in the other official language on one of those other surfaces.

(9) Subsection (2) does not apply to the identity and principal place of business of the person by or for whom the food was manufactured, processed, produced or packaged for resale if this information is shown in one of the official languages.

(10) Subsection (2) does not apply to the following common names if the common name appears on the principal display panel in the following manner:

Scotch Whisky
Irish Whisky
Highland Whisky
Dry Gin
Bourbon
15-12-93 † Tennessee Whisky
Tequila
15-12-93 ‡ Mezcal
Rye Whisky
Crème de Menthe
Crème de Cacao
Crème de Cassis
Crème de Banane
20-1-77 Triple Sec
Anisette
Crème de Noyau
Brandy
Sake or Saki
21-12-78 Advocaat or Advokaat
Kirsch
Slivovitz
Ouzo
Cherry Brandy Liqueur
Kummel
Akvavit
Aquavit
Armagnac
Marc
Grappa
Calvados
Poire William
Crème de Bleuets
Curaçao Orange
Liqueur de Fraise
Mandarinette
Prunelle de Bourgogne
Chartreuse
Pastis
Fior D'alpe
Strega
Campari
Americano
Apricot Brandy Liqueur
Peach Brandy Liqueur
Sloe Gin
Manhattan
Martini

† **Note**: Subsection **B.01.012**(10)† concerning Tenessee Whisky shall come into force on the day on which section 10 of *An Act to implement the North American Free Trade Agreement*, being chapter 44 of the Statutes of Canada, 1993, comes into force.

‡ **Note**: Subsection **B.01.012**(10)‡ concerning Mezcal shall come into force on the day on which section 10 of *An Act to implement the North American Free Trade Agreement*, being chapter 44 of the Statutes of Canada, 1993, comes into force or ninety days after the day on which the official standard for mezcal is made obligatory by the Government of Mexico, whichever is later.

12-7-79 (11) Subsection (2) does not apply to the label of a shipping container destined to a commercial or industrial enterprise or institution if,

(a) the shipping container and its contents are not resold as a one unit prepackaged product to a consumer at the retail level; and

20-1-77 (b) all information required by these Regulations to be shown on a label of a food is shown in one of the official languages.

B.01.013. (1) Unless specifically required by the Act or these Regulations, no reference, direct or indirect, to the Act or to these Regulations shall be made on any label of, or in any advertisement for, a food.

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(2) Notwithstanding subsection (1), where a food complies with a standard established by these Regulations and the manufacturer of the food has substantiated, by means of the results of tests carried out before the statement is made or by other evidence that exists before the statement is made, that the food so complies, a statement that the food "complies with the standard for (naming the common name of the food in respect of which the claim is made) in the *Food and Drug Regulations* " may be made on the label of, or in an advertisement for, the food.

B.01.014. The label of a food, other than a sweetener, that contains aspartame shall carry the following information:

(a) subject to paragraph (b), a statement on the principal display panel to the effect that the food contains aspartame or is sweetened with aspartame, in letters of at least the same size and prominence as the letters used in the numerical portion of the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*;

(b) in the case where other sweeteners are used in conjunction with aspartame, a statement on the principal display panel to the effect that the food

(I) contains aspartame and (naming the other sweeteners), or

(ii) is sweetened with aspartame and (naming the other sweeteners),

in letters of at least the same size and prominence as the letters used in the numerical portion of the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*;

(c) a statement on any part of the label to the effect that aspartame contains phenylalanine; and

31-10-88 (d) a statement setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence on any part of the label:

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the aspartame content, expressed in milligrams.

12-12-02 * (d) a statement setting out the aspartame content expressed in milligrams per serving of stated size.

23-7-81 **B.01.015.** (1) The label of a food that is a sweetener that contains aspartame shall carry the following information:

(a) a statement on the principal display panel to the effect that the food contains aspartame or is sweetened with aspartame, in letters of at least the same size and prominence as the letters used in the numerical portion of the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*;

(b) a statement on any part of the label to the effect that aspartame contains phenylalanine;

(c) a statement on any part of the label of the sweetness per serving expressed in terms of the amount of sugar required to produce an equivalent degree of sweetness; and

31-10-88 (d) a statement setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence on any part of the label:

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the aspartame content, expressed in milligrams.

12-12-02 * (d) a statement setting out the aspartame content expressed in milligrams per serving of stated size.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

(2) The label of a sweetener that contains aspartame may carry the expression "Low Calorie" if the energy value of a serving of the sweetener that is equivalent in sweetness to one teaspoon (5 g) of sugar is no greater than two calories.

6-10-94 **B.01.016.** The label of a food, other than a table-top sweetener, that contains sucralose shall carry the following information:

5-9-91 (a) subject to paragraph (b), a statement on the principal display panel to the effect that the food contains sucralose or is sweetened with sucralose, in letters of at least the same size and prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*;

5-9-91 (b) where sucralose is used in conjunction with another sweetener or a sweetening agent or both, the names thereof shown in a statement on the principal display panel to the effect that the food contains, or is sweetened with, sucralose and the other sweetener or the sweetening agent or both, as the case may be, in letters as described in paragraph (a); and

(c) a statement setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence, on any part of the label, namely,

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the sucralose content, expressed in milligrams.

12-12-02 * (c) a statement setting out the sucralose content expressed in milligrams per serving of stated size.

6-10-94 **B.01.017.** (1) The label of a food that is a table-top sweetener that contains sucralose shall carry the following information:

(a) a statement on the principal display panel to the effect that the food contains sucralose or is sweetened with sucralose, in letters of at least the same size and prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*;

(b) a statement on any part of the label setting out the sweetness per serving expressed in terms of the amount of sugar required to produce an equivalent degree of sweetness; and

5-9-91 (c) a statement setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence on any part of the label, namely,

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ)

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the sucralose content, expressed in milligrams.

12-12-02 * (c) a statement setting out the sucralose content expressed in milligrams per serving of stated size.

(2) The label of a food that is a table-top sweetener that contains sucralose may carry the words "Low Calorie" if the energy value of a serving of the sweetener that is equivalent in sweetness to one teaspoon (5 g) of sugar is no greater than two calories.

20-11-97 **B.01.018.** The label of a food that contains one or more of hydrogenated starch hydrolysates, isomalt, lactitol, maltitol, maltitol syrup, mannitol, sorbitol, sorbitol syrup, xylitol and polydextrose shall carry a statement, in which such of these as are in the food are grouped together, that sets out their content in the food, expressed in grams per serving of stated size.

12-12-02 * **B.01.018.** The label of a food that contains polydextrose shall indicate the amount of polydextrose expressed in grams per serving of stated size.

B.01.019. The label of a food, other than a table-top sweetener, that contains acesulfame-potassium shall carry the following information:

(a) subject to paragraph (b), a statement on the principal display panel to the effect that the food contains acesulfame-potassium or is sweetened with acesulfame-potassium, in letters of at least the same size and prominence as the characters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*;

(b) where acesulfame-potassium is used in conjunction with another sweetener or a sweetening agent or both, the names thereof shown in a statement on the principal display panel to the effect that the food contains, or is sweetened with, acesulfame-potassium and the other sweetener or the sweetening agent or both, as the case may be, in letters as described in paragraph (a); and

6-10-94 (c) a statement, on any part of the label, setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence, namely,

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the acesulfame-potassium content, expressed in milligrams.

12-12-02 * (c) a statement setting out the acesulfame-potassium content expressed in milligrams per serving of stated size.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

B.01.020. (1) The label of a food that is a table-top sweetener that contains acesulfame-potassium shall carry the following information:

(a) a statement, on the principal display panel, to the effect that the food contains acesulfame-potassium or is sweetened with acesulfame-potassium, in letters of at least the same size and prominence as the characters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*;

(b) a statement, on any part of the label, setting out the sweetness per serving, expressed in terms of the amount of sugar required to produce an equivalent degree of sweetness; and

6-10-94 (c) a statement, on any part of the label, setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence, namely,

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the acesulfame-potassium content, expressed in milligrams.

12-12-02 * (c) a statement setting out the acesulfame-potassium content expressed in milligrams per serving of stated size.

(2) The label of a food that is a table-top sweetener that contains acesulfame-potassium may carry the word "Low-Calorie" if the energy value of a serving of the sweetener that is equivalent in sweetness to one teaspoon (5 g) of sugar is no greater than two calories.

B.01.021. (1) The label of a food that contains erythritol shall carry a statement indicating the amount of erythritol expressed in grams per serving of stated size unless the label carries a nutrition facts table.

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(2) The statement of the amount of erythritol shall be grouped together with the statement of the amount of any other sugar alcohols and the amount of polydextrose.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

B.01.033. (1) Except in the case of infant formula or a formulated liquid diet, no person shall sell a food represented in any manner as containing hydrolyzed or partially hydrolyzed collagen, hydrolyzed or partially hydrolyzed gelatin or hydrolyzed or partially hydrolyzed casein unless the label carries the following statement on the principal display panel in the same size type used for the common name:

"CAUTION, DO NOT USE AS SOLE SOURCE OF NUTRITION".

12-1-78 (2) In this section, "formulated liquid diet" means a food that meets the requirements of sections B.24.101 to B.24.103.

B.01.034. Revoked by P.C. 1988-2457 of October 31, 1988

B.01.035. (1) Subject to subsection (8), where an irradiated food referred to in column I of the table to Division 26 is offered for sale as a prepackaged product, the principal display panel of the label applied to the package shall carry the symbol described in subsection (5).

(2) Where an irradiated food referred to in column I of the table to Division 26 is not a prepackaged product and is offered for sale, a sign that carries the symbol described in subsection (5) shall be displayed immediately next to the food.

(3) The symbol required pursuant to subsection (1) or (2) shall appear in close proximity on the principal display panel referred to in subsection (1) or on the sign referred to in subsection (2) to one of the following statements or a written statement that has the same meaning:

(a) "treated with radiation";
(b) "treated by irradiation"; or
(c) "irradiated".

(4) No person shall sell a food referred to in column I of the table to Division 26 that has been irradiated in the manner set out in subsection B.26.003(2) unless the requirements of subsections (1) to (3) are met.

(5) For the purposes of subsections (1) to (3), the symbol that indicates the irradiated food shall

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(a) have an outer diameter
  (i) in the case referred to in subsection (1), equal to or greater than the height of the numerical quantity prescribed by section 14 of the *Consumer Packaging and Labelling Regulations* for the declaration of net quantity of the package, and
  (ii) in the case referred to in subsection (2), not less than 5 cm; and
(b) be in the following form:



(6) Notwithstanding subsection B.01.009(1), any food referred to in column I of the table to Division 26 that is an ingredient or component of a prepackaged product and that has been irradiated shall, if the food constitutes ten per cent or more of the prepackaged product, be included in the list of ingredients and preceded by the statement "irradiated".

(7) The label attached to a shipping container containing any food referred to in column I of the table to Division 26 that has been subjected to the maximum permitted absorbed dose set out in column IV of that table shall carry the statement required by subsection (3) and the statement "Do not irradiate again".

(8) Where a shipping container constitutes the package of the prepackaged product, the label attached to the shipping container shall carry the statement required by subsection (7) but need not carry the symbol required by subsection (5).

23-3-89 (9) Any advertising of an irradiated food referred to in column I of the table to Division 26 shall identify the food as having been irradiated.

(10) The statements referred to in subsections (3) and (6) to (8) shall be in both official languages in accordance with subsection B.01.012(2).

31-10-88 **B.01.037.** Revoked by P.C. 1988-2457 of October 31, 1988

B.01.040. Revoked by P.C. 1988-2457 of October 31, 1988

B.01.042. Where a standard for a food is prescribed in this Part

(a) the food shall contain only the ingredients included in the standard for the food;

(b) each ingredient shall be incorporated in the food in a quantity within any limits prescribed for that ingredient; and

(c) if the standard includes an ingredient to be used as a food additive for a specified purpose, that ingredient shall be a food additive set out in one of the Tables to section B.16.100 for use as an additive to that food for that purpose.

6-11-87 **B.01.043.** Subject to section B.25.062, where a standard for a food is not prescribed in this Part,

(a) the food shall not contain any food additives except food additives set out in a Table to section B.16.100 for use as additives to that food for the purpose set out in that Table; and

10-11-76 (b) each such food additive shall be incorporated in the food in a quantity within any limits prescribed for that food and food additive in that Table.

B.01.044. Where the limit prescribed for a food additive in a Table to section B.16.100 is stated to be "Good Manufacturing Practice", the amount of the food additive added to a food in manufacturing and processing shall not exceed the amount required to accomplish the purpose for which that additive is permitted to be added to that food.

B.01.045. A food additive shall,

12-3-74 (a) where specifications are set out in this Part for that additive, meet those specifications, and

20-11-97 (b) where no specifications are set out in this Part for that additive but specifications are set out for it in the *Food Chemicals Codex*, Fourth Edition, 1996, published by the National Academy of Sciences, Washington, D.C., United States, as amended from time to time, meet those specifications;

14-12-94 (c) in the case of lactitol and maltitol, meet the specifications established by the Joint FAO/WHO Expert Committee on Food Additives as set out in the *Specifications for identity and purity of certain food additives - FAO Food and Nutrition 38*, published in 1988 by the Food and Agriculture Organization of the United Nations, Rome; and

6-2-92 (d) in the case of sucrose esters of fatty acids, meet the specifications established by the Joint FAO/WHO Expert Committee on Food Additives as set out in the *Specifications for identity and purity of certain food additives - FAO Food and Nutrition 49* published in 1990 by the Food and Agriculture Organization of the United Nations, Rome; and

20-11-97 (e) in the case of isomalt, meet the specifications established by the Joint FAO/WHO Expert Committee on Food Additives as set out in the *Compendium of food additive specifications, Addendum 4 - FAO Food and Nutrition Paper 52*, published in 1996 by the Food and Agriculture Organization of the United Nations, Rome.

3-9-64 **B.01.046.** (1) A food is adulterated if any of the following substances or classes of substances are present therein or have been added thereto:

2-12-82 (a) mineral oil, paraffin wax or petrolatum or any preparation thereof;

3-9-64 (b) coumarin, an extract of tonka beans, the seed of *Dipteryx Odorata* Willd. or *Dipteryx oppositifolia* Willd.;

15-9-77 (c) non-nutritive sweetening agents;

(d) cottonseed flour that contains more than four hundred and fifty parts per million of free gossypol;

(e) fatty acids and their salts containing chick-edema factor or other toxic factors;

(f) dihydrosafrole;

(g) isosafrole;

3-9-64 (h) oil of American sassafras from *Sassafras albidum* (Nutt). Nees;

(i) oil of Brazilian sassafras from *Ocolea cymbarum* H.B.K.;

12-4-84 (j) oil of camphor sassafrassy from *Cinnamomum camphorum* Sieb.;

(k) oil of micranthum from *Cinnamomum micranthum* Hayata;

(l) safrole, or

25-2-69 (m) oil, extract or root of calamus from *Acorus calamus* L.

(n) nut and nut products that contain more than fifteen parts per billion of aflatoxin;

10-11-76 (o) ethylene thiourea;

26-6-80 (p) chlorinated dibenzo-p-dioxins; or

3-11-83 (q) cinnamyl anthranilate.

17-10-88 (2) For the purpose of paragraph (1)(n), the aflatoxin content of a nut or nut product shall be calculated on the basis of the nut meat portion.

15-9-77 **B.01.046.B.** Revoked by P.C. 1977-2549 of September 15, 1977.

B.01.047. Notwithstanding section B.01.046.

12-11-81 (a) a food, other than sausage casing, is not adulterated by reason only that it contains 0.3 per cent or less mineral oil, if good manufacturing practice requires the use of mineral oil;

(b) chewing gum is not adulterated by reason only that it contains a paraffin wax base;

(c) fresh fruits and vegetables, except turnips, are not adulterated by reason only that they are coated with not more than 0.3 per cent paraffin wax and petrolatum, if good manufacturing practices require the use of such coating;

3-9-64 (d) turnips and cheese are not adulterated by reason only that they are coated with paraffin wax in accordance with good manufacturing practice;

12-11-81 (e) sausage casing is not adulterated by reason only that it contains five per cent or less mineral oil by weight, if good manufacturing practice requires the use of mineral oil;

14-01-82 (f) fish is not adulterated by reason only that it contains 20 parts per trillion or less of 2,3,7,8-tetrachloro-dibenzoparadioxin;

8-12-83 (g) bakery products and confectionery are not adulterated by reason only that they contain 0.15 per cent or less petrolatum, if good manufacturing practice requires the use of petrolatum; and

15-12-83 (h) a salt substitute is not adulterated by reason only that it contains 0.6 per cent or less mineral oil, if good manufacturing practice requires the use of mineral oil.

23-1-92 (i) fruits, vegetables and cereals are not adulterated by reason only that they contain 0.05 parts per million or less of ethylene thiourea.

B.01.047.1 (1) The following definitions apply in this section.

"BSE" means bovine spongiform encephalopathy. (*ESB*)

"specified risk material" means

(a) the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord and dorsal root ganglia of cattle aged 30 months or older; and

(b) the distal ileum of cattle of all ages. (*matériel à risque spécifié*)

23-7-03 (2) No person shall sell or import for sale food that contains specified risk material.

(3) Subsection (2) does not apply in respect of food that originates from a country that is designated as being free from BSE in accordance with section 7 of the *Health of Animals Regulations*.

(4) Subsection (2) does not apply in respect of food that is packaged for sale or imported for sale before the day on which this subsection comes into force.

B.01.048. (1) No person shall sell

(a) any animal intended for consumption as food if any product containing any drug listed in subsection (2) has been administered to the animal;

16-8-94 (b) any meat, meat by-products, eggs or milk intended for consumption as food and derived from an animal if any product containing any drug listed in subsection (2) has been administered to that animal; or

(c) any meat, meat by-products, eggs or milk that contains any residue of any drug listed in subsection (2).

(2) The drugs referred to in subsection (1) are

20-11-97 (a) chloramphenicol and its salts and derivatives;

(b) a 5-nitrofuran compound;

(c) clenbuterol and its salts and derivatives;

13-8-03 (d) a 5-nitroimidazole compound; and

(e) diethylstilbestrol and other stilbene compounds.

23-10-73 **B.01.049.** No person shall use, in labelling, packaging, advertising or selling a food that does not meet the requirements of the kashruth applicable to it, the word 'kosher' or any letters of the Hebrew alphabet or any other word, expression, depiction, sign, symbol, mark, device or other representation that indicates or that is likely to create an impression that the food is kosher.

8-9-66 **B.01.053.** No person shall sell a product represented as ready breakfast or instant breakfast or by any similar designation unless each portion or serving of the product contains

12-12-02 **B.01.053.** * No person shall sell a product represented as a ready breakfast or instant breakfast or by any similar designation unless each serving of stated size of the product contains

8-9-66 (a) not less than 4.0 mg iron;

(b) Vitamin A, thiamine, riboflavin, niacin or niacinamide and Vitamin C;

(c) a good dietary source of protein; and

(d) where consumed as directed, not less than 300 calories.

21-3-85 **B.01.054.** (1) In order to generate information in support of an amendment to the Regulations, the Director may issue to the manufacturer or distributor of a food, where the food or the packaging, labelling or advertising of the food does not comply with the requirements of these Regulations, a Temporary Marketing Authorization Letter that authorizes the sale of the food described therein or the packaging, labelling or advertising of the food described therein for a specified period of time, within a designated area and in a specified quantity, in the manner specified in the Letter if

(a) the manufacturer or distributor of the food has supplied to the Director the following information:

(i) the purpose for which the temporary marketing authorization of the food is required,

(ii) a description of the food including a sample and proposed label,

(iii) a description of any proposed variation from the requirements of these Regulations,

9-7-81 (iv) adequate data to show that the use of the food will not be detrimental to the health of the purchaser or user,

(v) the proposed quantity of the food to be sold,

(vi) the proposed period of time required for such sale,

(vii) the proposed area designated for such sale, and

(viii) such other data as the Director may require; and

(b) the manufacturer or distributor of the food has agreed to

(i) describe the food on a label or in an advertisement in a manner that is not false, misleading or deceptive,

21-3-85 (ii) use such marks or statements on the label or in any advertisement as the Director may require,

(iii) on request, submit to the Director results of the temporary marketing, and

(iv) on request, withdraw the product from sale where the Director is of the opinion that it is in the public interest to do so.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

(2) The Director shall, in any Temporary Marketing Authorization Letter issued pursuant to subsection (1), set out

(a) the common name and description of the food to be sold;
(b) the name and address of the manufacturer or distributor of the food;
(c) the purpose for which the temporary marketing of the food is authorized;
(d) the quantity of the food that is authorized for sale;
21-3-85 (d.1) the type of packaging, labelling or advertising authorized in respect of the food where the Letter is intended to authorize a variation from a requirement of any provision of the Regulations respecting packaging, labelling or advertising;
(e) the period of time during which the food may be sold; and
9-7-81 (f) the designated area within which the food may be sold.

21-3-85 **B.01.055.** (1) A manufacturer or distributor named in a Temporary Marketing Authorization Letter issued pursuant to subsection B.01.054(1) may, for the purpose set out in the Letter, sell the food in the manner authorized in the Letter and package, label or advertise that food in the manner authorized in the Letter for the period of time, within the designated area and in the quantity set out in the Letter.

22-11-90 (2) No provision of these Regulations made pursuant to paragraph 30(1)(b) of the Act applies in respect of a food or the packaging, labelling or advertising of a food for which a Temporary Marketing Authorization Letter has been issued pursuant to subsection B.01.054(1) to the extent that the food, or the packaging, labelling or advertising of the food, as authorized in the Letter, does not comply with that provision.

B.01.056. (1) Notwithstanding sections B.01.042 and B.01.043, where a food does not comply with the requirements of these Regulations, the manufacturer or distributor of the food, or of a food additive, agricultural chemical, veterinary drug, vitamin, mineral nutrient or amino acid present in the food, may make a written request to the Director

(a) for the exemption of the food from the application, in whole or in part, of the requirements relating to it under these Regulations;
(b) for a Notice of Interim Marketing Authorization concerning the food that confirms the exemption; and
(c) that these Regulations be amended.

(2) For the purpose of this section, a food does not comply with the requirements of these Regulations if

3-7-97 (a) any of the following is present in the food:
  (i) a food additive that is
    (A) set out in column I of an item of any of the tables to section B.16.100 in an amount that exceeds the maximum level of use set out in column III or IV of that item in respect of that food, or
    (B) not included in the standard for that food in these Regulations,
  (ii) an agricultural chemical, or any of its derivatives, set out in column I of an item of Table II to Division 15 of Part B, in an amount that exceeds the maximum residue limit set out in column III of that item,
  (iii) a veterinary drug set out in column I of an item of Table III to Division 15 of Part B in an amount that exceeds the maximum residue limit set out in column III of that item,
  (iv) an ingredient in a form other than the form described in the standard for that food in these Regulations, or
  (v) a vitamin, mineral nutrient or amino acid
    (A) that is not set out in the Table to Section D.03.002, or
    (B) the level of use of which is at variance with the level permitted under these Regulations;
(b) the food
  (i) is not set out in column IV of Table II to Division 15 of Part B and contains an agricultural chemical or any of its derivatives set out in column I of that Table,
  (ii) is not set out in column IV of Table III to Division 15 of Part B and contains a veterinary drug set out in column I of that Table, or
  (iii) is not set out in column II of any of Tables I to IV and VI to XV or in column III of Table V to section B.16.100, and contains a food additive set out in column I of that Table.

(3) The request referred to in subsection (1) shall be accompanied by the following information:

(a) the common name and description of the food;
(b) the reasons for which the exemption, the Notice of Interim Marketing Authorization and an amendment to these Regulations are required;
(c) a description of every proposed variation from the requirements of these Regulations;
3-7-97 (d) adequate data, including results of tests and scientific analysis, that demonstrate that the use of the food will not be detrimental to the health of the purchaser or user; and
(e) where the request relates to the addition of a vitamin, mineral nutrient or amino acid to the food, a statement, with supporting documentation, as to the consistency of the request with the General Principles for the Addition of Essential Nutrients to Foods adopted by the Joint Food and Agriculture Organization of the United Nations / World Health Organization Codex Alimentarius Commission and published in the *Codex Alimentarius* (Rome, 1996), as amended from time to time.

(4) Where the Director determines after examining the request and the information submitted under subsection (3) that use of the food will not be harmful to the health of the purchaser or user, the Director shall exempt the food from the application, in whole or in part, of the requirements relating to it under these Regulations and issue a conditional or unconditional Notice of Interim Marketing Authorization relating to the food. The Director shall also indicate his or her intention to recommend that these Regulations be amended in relation to the food.

(5) The Notice of Interim Marketing Authorization issued under subsection (4) shall set out

(a) the common name and description of the food;
(b) the reasons for which the exemption is established and the Notice of Interim Marketing Authorization issued; and
(c) such of the following as are applicable to the food:
  (i) the maximum residue limit of any agricultural chemical or any of its derivatives, expressed in parts per million,
  (ii) the maximum level of use of any food additive that the food is permitted to contain, or have on it, expressed in the applicable units of measurement,
  (iii) the maximum residue limit of any veterinary drug, expressed in parts per million, and
  (iv) the minimum and maximum limits for the addition of any vitamin, mineral nutrient or amino acid, expressed in the applicable units of measurement.

(6) The Notice of Interim Marketing Authorization issued under subsection (4) must be published in the *Canada Gazette* Part I and has effect beginning on the date of publication.

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(7) The Director may, by a notice published in the *Canada Gazette* Part I, revoke an exemption and Notice of Interim Marketing Authorization relating to a food where the Director believes on reasonable grounds, after reviewing any information that comes to the attention of the Director, that use of the food is or may be harmful to the health of the purchaser or user.

(8) A Notice of Interim Marketing Authorization issued under subsection (4) in relation to a food loses its effect on the coming into force of any amendment to these Regulations resulting from the Director's recommendation referred to in that subsection.

31-10-88 | Sections **B.01.060.** to **B.01.066.** Revoked by P.C. 1988-2457 of October 31, 1988.

24-3-72 | **B.01.070. [S].** Mixed nuts or a mixture of nuts shall consist of a mixture of nuts in which not less than five per cent by weight of each type of nuts is present in the mixture.

B.01.071. Where a prepackaged product is a mixture of nuts, the percentage and common name of the nut that is present in the product in the greatest amount by weight shall be applied to the principal display panel of the package in close proximity to the common name of the product.

29-10-92

B.01.072. Notwithstanding any requirement prescribed in Part B, a food product that has been subjected to heat in the presence of a vaporized liquid solution of smoke derived from hardwood, hardwood sawdust or corn cobs may be described as "smoked".

20-1-77 | **B.01.080.** (1) In this section, "frozen" means preserved by freezing temperature and does not include any surface freezing that may occur during holding and transportation.

22-10-74 | (2) Where meat, meat by-products, poultry meat, poultry by-products or fish, or meat of any marine or fresh water animal, that has been frozen is thawed prior to sale, the words "previously frozen" shall be shown

(a) on the principal display panel in close proximity to the common name of the food and in letters at least as legible and conspicuous as those used in the common name;

23-6-88 | (b) anywhere on the principal display panel in letters of not less than 1/4 of an inch (6.4 millimeters) in height; or

22-10-74 | (c) on a sign displayed adjacent to the food in letters that are legible and conspicuous to a prospective purchaser.

(3) Where part of a food referred to in subsection (2) has been frozen and thawed prior to sale, the words "Made from fresh and frozen portions" or "Made from fresh and frozen (naming the food)" shall be shown in the manner described in paragraph (2)(a), (b) or (c).

B.01.090. (1) No person shall offer for sale at retail any solid cut meat or solid cut poultry meat to which phosphate salts or water has been added, unless that meat or poultry meat is contained in a package and carries a label.

(2) The label referred to in subsection (1) shall contain a statement of the minimum percentage of meat protein as part of the common name of the product on the principal display panel of the package in type that is as legible and conspicuous as any other type on that display panel, and in letters that are at least one half of the size of the letters used in the common name of the product but that are not less than 1.6 mm in height.

24-3-94 **B.01.091.** (1) The label of any solid cut meat or solid cut poultry meat that has had phosphate salts or water added to it and that is prepackaged by the manufacturer shall carry, on any part thereof, except on the bottom of the container, a statement that sets out in a single grouping, in type at least as legible and conspicuous as any other type on that display panel and in letters that are at least one half of the size of the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations* but that are not less than 1.6 mm in height, the following energy value and contents of the food, per 100 g serving:

(a) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ); and
(b) the protein, fat and carbohydrate content, expressed in grams.

(2) Where a food described in subsection B.01.090(1) is not cured and is cooked, sliced or cut up for sale at a retail meat counter, the label for that food shall contain a statement of the ingredients contained in that product in accordance with subsections B.01.008(3) to (5).

12-12-02 * **B.01.091.** The label of any solid cut meat or solid cut poultry meat that has had phosphate salts or water added to it, that is not cured and that is prepackaged at retail shall contain a statement of the ingredients contained in the food in accordance with subsections B.01.008(3) to (5).

B.01.092. Sections B.01.090 and B.01.091 do not apply in respect of side bacon, Wiltshire bacon, pork jowls, salt pork or salt beef.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

B.01.100. (1) The common name of a simulated meat product or simulated poultry product shall be the common name of the meat product or poultry product that is simulated, modified by the word "simulated".

(2) The word "simulated" in the common name of a simulated meat product or simulated poultry product shall be shown in letters of at least the same size and prominence as those used in the remainder of the common name of that product.

(3) Where a simulated meat product or a simulated poultry product is not a prepackaged product, the common name of the product and the other information required by this section to be shown on the label of a simulated meat product or simulated poultry product shall be shown on a sign displayed on or adjacent to the product in letters that are legible and conspicuous to a prospective purchaser.

(4) The words

(a) "contains no meat", in the case of a simulated meat product, and
(b) "contains no poultry", in the case of a simulated poultry product,

shall be shown on the principal display panel of the label of a simulated meat product or simulated poultry product in close proximity to the common name and in letters of at least the same size and prominence as those shown in the common name.

31-10-88 Subsections (5) to (7), revoked by P.C. 1988-2457 of October 31, 1988.

B.01.100A. Section B.01.100 does not apply until March 1, 1976 to

(a) a simulated meat product, or
(b) a simulated poultry product that was,

prior to the coming into force of these Regulations, being sold in Canada.

B.01.101. (1) For the purposes of this section and section B.01.102, "source of protein" means any food that contains protein, but does not include spices, seasonings, flavours, artificial flavours, flavour enhancers, food additives and similar foods that contain only small amounts of protein.

(2) The common name of a meat product extender shall be the common name of each food in the meat product extender that is a source of protein, plus

(a) the word "meat", or the common name of the meat product that is to be extended, plus the word "extender", or
(b) the words "extender for" plus the common name of the meat product that is to be extended.

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(3) The common name of a poultry product extender shall be the common name of each food in the poultry product extender that is a source of protein, plus

(a) the word "poultry", or the common name of the poultry product that is to be extended plus the word "extender"; or
(b) the words "extender for " plus the common name of the poultry product that is to be extended.

(4) Foods that are a source of protein in the meat product extender or poultry product extender shall be shown by their common names in the common name of that meat product extender or poultry product extender

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(a) in descending order of their proportion of the meat product extender or poultry product extender; and
(b) in letters of at least the same size and prominence as those used in the remainder of the common name of the meat product extender or poultry product extender.

31-10-88 Subsections (5) and (6), revoked by P.C. 1988-2457 of October 31, 1988.

B.01.102. (1) The common name of an extended meat product or an extended poultry product shall be the common name of the meat product or poultry product that is extended, modified by the common name of each of the foods that are sources of protein in the extended meat product or extended poultry product.

(2) Notwithstanding subsection (1),

(a) the word or words "meat", "meat product", "poultry", "poultry meat" or "poultry meat by-product" as the case may be, may be used in the common name of an extended meat product or extended poultry product as the common name of the food therein that is a source of protein derived from a meat product or poultry product, and

(b) where it is an acceptable manufacturing practice for a manufacturer to omit from his meat product extender or poultry product extender any source of protein derived from a plant that is ordinarily an ingredient of that meat product extender or poultry product extender, or to substitute in whole or in part in his meat product extender or poultry product extender any source of protein derived from a plant for a source of protein that is ordinarily an ingredient of that meat product extender or poultry extender, the word "plant" may be used in the common name of an extended meat product or extended poultry product as the common name of the food therein that is a source of protein derived from a plant.

(3) Foods that are a source of protein in an extended meat product or extended poultry product shall be shown by their common names in the common name of that product

(a) in descending order of their proportion of that product, and
(b) in letters of at least the same size and prominence as those used in the remainder of the common name of that product.

(4) Where an extended meat product or extended poultry product is not a prepackaged product, the common name of that product and the information required by this section to be shown on the label of an extended meat product or extended poultry product shall be shown on a sign displayed on or adjacent to that product in letters that are legible and conspicuous to a prospective purchaser.

31-10-88 Subsections (5) to (7), revoked by P.C. 1988-2457 of October 31, 1988.

29-7-75 **B.01.103.** (1) The common name of a yolk-replaced egg shall be "yolk-replaced egg".

31-10-88 Subsections (2) to (4), revoked by P.C. 1988-2457 of October 31, 1988.

B.01.300. (1) No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim relating to the content in the food of one or more of the following substances, namely,

(a) protein,
(b) fat,
(c) carbohydrate,
(d) sugars,
(e) sorbitol,
(f) mannitol,
(g) xylitol,
31-10-88 (h) starch,
(i) dietary fibre, and
(j) amino acids

unless the content of the substance to which the statement of claim relates is declared in grams per serving of stated size.

(2) Subsection (1) does not apply in respect of

(a) a statement in a list of ingredients that lists any of the substances referred to in paragraphs (1)(a), (b), (d), (e), (f), (g), (h) or (j); or
(b) a statement or claim in respect of a food containing a substance referred to in paragraph (1)(c) or (d) that is a statement or claim to the effect that the food is reduced in or free of lactose.

12-12-02 | * **B.01.300.** Repealed by P.C. 2002-2200 of December 12, 2002.

31-10-88 | **B.01.301.** No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim relating to the energy value of the food unless a declaration of the energy value, preceded by the word "energy", expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ) per serving of stated size, is made.

| * **B.01.301.** (1) No person shall, on the label of or in any advertisement for a food, other than in the nutrition facts table, if any, include a declaration of the food's energy value or the amount of a nutrient contained in the food unless it is declared in the following manner, per serving of stated size:

(a) in the case of the energy value, in Calories;
(b) in the case of a vitamin set out in column I of Table I to Division 1 of Part D or a mineral nutrient set out in column I of Table I to Division 2 of Part D, in the units specified in that column;
(c) in the case of sodium, potassium or cholesterol, in milligrams;
(d) in the case of the mineral ion content of prepackaged water or ice, in parts per million; and
(e) in any other case, in grams.

12-12-02 | (2) Despite subsection (1), a person may, on the label of a food or in any advertisement for a food, other than in the nutrition facts table, if any, include a declaration of the percentage of the daily value of a nutrient contained in the food if

(a) the nutrient is listed in column 1 of the table to section B.01.401 or the table to section B.01.402;
(b) the percentage of the daily value of the nutrient is required or permitted to be declared in the nutrition facts table; and
(c) the percentage of the daily value of the nutrient is declared per serving of stated size.

(3) A declaration referred to in subsection (1) or (2) that appears on the label of a food shall be

(a) in English and French; or
(b) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

| **B.01.302.** (1) No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim relating to the sodium or potassium content of the food unless a declaration of the sodium and potassium content, expressed in milligrams per serving of stated size, is made.

31-10-88 | (2) For the purposes of subsection (1), a statement or claim relating to the salt content of a food, other than a statement in the list of ingredients, is a statement or claim relating to the sodium content of the food.

29-11-90 | **B.01.303.** (1) No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a meal replacement for weight reduction diets, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim relating to the fatty acid or cholesterol content of the food unless a declaration is made of

(a) the content of fat, cis-methylene interrupted polyunsaturated fatty acids, cis-monounsaturated fatty acids and saturated fatty acids, expressed in grams per serving of stated size; and
31-10-88 | (b) the cholesterol content, expressed in milligrams per serving of stated size.

(2) In a declaration required by subsection (1),

(a) cis-methylene interrupted polyunsaturated fatty acids shall be referred to as "polyunsaturates";
(b) cis-monounsaturated fatty acids shall be referred to as "monounsaturates"; and
(c) saturated fatty acids shall be referred to as "saturates".

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

31-10-88 **B.01.304.** The information required in a declaration referred to in any of sections B.01.300 to B.01.303 shall be

(a) grouped together in a prominent and readily discernible manner; and
(b) given
  (i) on the label, where the statement or claim is made on the label, or
  (ii) in the advertisement or on the label, where the statement or claim is made in an advertisement.

12-12-02 * **B.01.302. to B.01.304** of the Regulations are repealed by P.C. 2002-2200 of December 12, 2002.

B.01.305. (1) No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, use the word "protein", the expression "amino acid" or the name of any protein or amino acid or make any claim in respect of proteins or amino acids collectively or by name unless

(a) where the food is a breakfast cereal, 30 grams of the product plus 125 millilitres of milk have a protein rating of not less than 20; and
(b) where the food is not a breakfast cereal, the amount of the food that is ordinarily consumed in a reasonable daily intake has a protein rating of not less than 20.

31-10-88 (2) For the purposes of paragraphs (1)(a) and (b), the protein rating shall be determined by official method FO-1, *Determination of Protein Rating*, dated October 15, 1981.

(3) Subsection (1) does not apply in respect of

(a) the word "protein" when used as part of the common name of an ingredient;
(b) the declaration of amino acids in a list of ingredients;
(c) single amino acid preparations that may be sold as foods;
(d) the statements required by paragraphs B.01.014(c) and B.01.015(b);
(e) foods represented for use in gluten-free diets;
(f) foods represented for use in protein-restricted diets;
(g) foods represented for use in low (name of the amino acid) diets; or
(h) a statement of the amount of protein contained in a food.

* **B.01.305.** (1) No person shall, on the label of or in any advertisement for a food, make a representation, express or implied, respecting a protein unless the food meets the conditions set out in column 2 of item 8 of the table following section B.01.513 for the subject "source of protein" set out in column 1.

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(2) No person shall, on the label of or in any advertisement for a food, make a representation, express or implied, respecting an amino acid unless

(a) the food meets the conditions set out in column 2 of item 8 of the table following section B.01.513 for the subject "source of protein" set out in column 1; and
(b) the label or advertisement includes a declaration of the amount of histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan and valine contained in the food, expressed in grams per serving of stated size.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

(3) Subsections (1) and (2) do not apply in respect of

(a) a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute;
(b) foods represented for use in gluten-free diets, protein restricted diets, low (naming the amino acid) diets and (naming the amino acid) free diets;
(c) the word "protein" when used as part of the common name of an ingredient in the list of ingredients;
12-12-02 (d) the declaration of amino acids in the list of ingredients;
(e) the common names set out in column II of items 7 to 9 of the table to paragraph B.01.010(3)(a), when shown in the list of ingredients in accordance with that paragraph;
(f) the common name of a single amino acid preparation that may be sold as a food;
(g) the statements required by paragraphs B.01.014(c) and B.01.015(1)(b);
(h) a statement or claim set out in column 4 of item 7 of the table following section B.01.513 respecting the subject "low in protein" set out in column 1;
(i) a declaration of the amount of protein in the nutrition facts table;
(j) a statement of the protein content of a food as required by paragraph B.24.103(c), subparagraph B.24.202(a)(ii), paragraph B.24.304(b) or B.25.057(1) (a) or subparagraph B.25.057(2) (c) (i) or (d) (i); or
(k) a statement that a food is not a source of protein.

(4) A representation referred to in subsection (1) or (2) that appears on the label of a food shall be

(a) in English and French; or
(b) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

B.01.306. (1) Subject to subsection (2) and section B.01.306.1, no person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a food represented for use in a very low-energy diet, a meal replacement, a nutritional supplement, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim regarding the presence in the food of a specific fatty acid other than linoleic acid, or of a specific group of fatty acids other than *cis*-methylene interrupted polyunsaturated fatty acids, *cis*-monounsaturated fatty acids and saturated fatty acids.

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(2) No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a food represented for use in a very low-energy diet, a meal replacement, a nutritional supplement, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim relating to the linoleic acid content of the food, unless a declaration is made of

31-10-88 (a) the content of fat, linoleic acid, *cis*-methylene interrupted polyunsaturated fatty acids, *cis*-monounsaturated fatty acids and saturated fatty acids, expressed in grams per serving of stated size; and
(b) the cholesterol content, expressed in milligrams per serving of stated size.

B.01.306.1 No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim, express or implied, that the food is low in saturated fatty acids or is a low-saturates food unless the food derives no more than 15 per cent of its energy value from saturated fatty acids and a serving of stated size of the food contains no more than 2 grams of saturated fatty acids.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

B.01.307. No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim, express or implied, that the food is low in cholesterol or is a low-cholesterol food unless the food

(a) contains no more than 20 milligrams of cholesterol per 100 grams and a serving of stated size of the food contains no more than 20 milligrams of cholesterol; and
(b) derives no more than 15 per cent of its energy value from saturated fatty acids and a serving of stated size of the food contains no more than 2 grams of saturated fatty acids.

B.01.308. No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim, express or implied, that the food is free of cholesterol or is a cholesterol-free food unless the food

(a) contains no more than 3 milligrams of cholesterol per 100 grams; and
(b) derives no more than 15 per cent of its energy value from saturated fatty acids and a serving of stated size of the food contains no more than 2 grams of saturated fatty acids.

31-10-88 **B.01.309.** No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim, express or implied, that the food is low in fat or is a low-fat food unless the food contains no more than 0.15 gram of fat per gram of dry matter and a serving of stated size of the food contains no more than 3 grams of fat.

B.01.310. Where the content in a food of any substance named in paragraphs B.01.300(1)(d) to (j) or of sodium, potassium, *cis*-methylee interrupted polyunsaturated fatty acids, *cis*-monounsaturated fatty acids, saturated fatty acids, cholesterol, linoleic acid or of any vitamin or mineral nutrient is declared in accordance with section B.01.300, B.01.301, B.01.302 or B.01.303 or subsection B.01.306(2) or section D.01.004, D.01.005, D.02.002 or D.02.003, it may be declared on any label or part of a label of the food, other than a label on the bottom of the container of the food, if the statement of content is grouped together with and given equal prominence as a declaration of

(a) the energy value of the food, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ) per serving of stated size; and
(b) the content in the food of protein, fat and carbohydrate, expressed in grams per serving of stated size.

12-12-02 * **B.01.306. to B.01.310** of the Regulations are repealed by P.C. 2002-2200 of December 12, 2002.

B.01.311. (1) Subject to subsection (2), no person shall, on the label of a food or in any advertisement for a food that is made to the general public, make any claim concerning the action or effects of any of the following substances contained in the food:

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(a) linoleic acid;
(b) *cis*-methylene interrupted polyunsaturated fatty acids;
(c) *cis*-monounsaturated fatty acids;
(d) saturated fatty acids; or
(e) a substance referred to in any of paragraphs B.01.300(1)(a) to (j).

(2) A claim referred to in subsection (1) may be made to the effect that the substance in respect of which the claim is made is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.

* COMING INTO FORCE: *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

*** B.01.311.** (1) Subject to subsections (2) and (3), no person shall, on the label of or in any advertisement for a food, make a representation, express or implied, concerning the action or effect of the food's energy value or of a nutrient contained in the food.

(2) The label of or advertisement for a food may carry a statement or claim set out in column 1 of the table following section B.01.603.

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(3) Subject to section B.01.312, the label of or advertisement for a food may carry a statement or claim to the effect that the food's energy value or a nutrient contained in the food is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.

(4) If a statement or claim described in subsection (3) concerns a nutrient not listed in column 1 of the tables to sections B.01.401 and B.01.402, the amount of the nutrient contained in the food must be expressed on any part of the label in grams per serving of stated size.

(5) A statement or claim referred to in subsection (2) or (3) that appears on the label of a food shall be

(a) in English and French; or
(b) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

*** COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

* **B.01.312.** (1) If a statement or claim described in subsection B.01.311 (3) is made on the label of or in an advertisement for a food that is not a prepackaged product or in an advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include a declaration, per serving of stated size, of

(a) the energy value, if the energy value is the subject of the statement or claim; or
(b) the amount of the nutrient, if a nutrient is the subject of the statement or claim.

(2) If the statement or claim is made in an advertisement other than a radio or television advertisement, the declaration referred to in subsection (1) shall be

(a) adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and

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(b) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

(3) If the statement or claim is made in a radio advertisement or in the audio portion of a television advertisement, the declaration referred to in subsection (1) shall immediately precede or follow the statement or claim.

(4) If the statement or claim is made in a television advertisement, the declaration referred to in subsection (1) shall be communicated

(a) in the audio mode, if the statement or claim is made only in the audio portion of the advertisement or in both the audio and visual portions; or
(b) in the audio or visual mode, if the statement or claim is made only in the visual portion of the advertisement.

(5) If the declaration referred to in subsection (1) is communicated in the visual mode of a television advertisement, it shall

(a) appear concurrently with and for at least the same amount of time as the statement or claim;
(b) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and
(c) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

*** COMING INTO FORCE : All sections B.01.400 to B.01.603.**

These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

Interpretation

***B.01.400.** The following definitions apply in sections B.01.401 to B.01.603.

"fat" means all fatty acids expressed as triglycerides. (*lipides*)

"point" means a unit of measurement for type size that is known as an Anglo-American point and is equal to 0.3514598 mm. (*point*)

Nutrition Labelling

Core Information

***B.01.401.** (1) Except as otherwise provided in this section and sections B.01.402 to B.01.406 and B.01.467, the label of a prepackaged product shall carry a nutrition facts table that contains only the information set out in column 1 of the table to this section expressed using a description set out in column 2, in the unit set out in column 3 and in the manner set out in column 4.

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(2) Subsection (1) does not apply to a prepackaged product if

(a) all the information set out in column 1 of the table to this section, other than in respect of item 1 ("Serving of stated size"), may be expressed as "0" in the nutrition facts table in accordance with this section;

(b) the product is

(i) a beverage with an alcohol content of more than 0.5%,

(ii) a fresh vegetable or fruit or any combination of fresh vegetables or fruits without any added ingredients, an orange with added food color or a fresh vegetable or fruit coated with paraffin wax or petrolatum,

(iii) a raw single ingredient meat, meat by-product, poultry meat or poultry meat by-product,

(iv) a raw single ingredient marine or fresh water animal product,

(v) sold only in the retail establishment where the product is prepared and processed from its ingredients, including from a pre-mix if an ingredient other than water is added to the pre-mix during the preparation and processing of the product,

(vi) sold only at a road-side stand, craft show, flea market, fair, farmers' market or sugar bush by the individual who prepared and processed the product,

(vii) an individual serving that is sold for immediate consumption and that has not been subjected to a process to extend its durable life, including special packaging, or

(viii) sold only in the retail establishment where the product is packaged, if the product is labelled by means of a sticker and has an available display surface of less than 200 cm^2; or

(c) the product is

(i) a prepackaged confection, commonly known as a one bite confection, that is sold individually,

(ii) a prepackaged individual portion of food that is solely intended to be served by a restaurant or other commercial enterprise with meals or snacks, or

(iii) milk, partly skimmed milk, skim milk, goat's milk, partly skimmed goat's milk, skimmed goat's milk, (naming the flavour) milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk or cream sold in a refillable glass container.

(3) Despite paragraphs (2) (a) and (b), subsection (1) applies to a prepackaged product if

(a) the product contains an added vitamin or mineral nutrient;
(b) a vitamin or mineral nutrient is declared as a component of one of the product's ingredients other than flour;
(c) the product contains added aspartame, sucralose or acesulfame-potassium;
(d) the product is a meat, meat by-product, poultry meat or poultry meat by-product that is ground; or
(e) the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product, contains
    (i) a reference to the energy value, a nutrient set out in column 1 of the table to this section or in column 1 of the table to section B.01.402 or a constituent of such a nutrient, other than information required by Division 12 or a reference to the common name of an ingredient in the list of ingredients for the product,
    (ii) a representation that expressly or implicitly indicates that the product has particular nutritional or health-related properties, including any statement or claim set out in column 4 of the table following section B.01.513 or column 1 of the table following section B.01.603 or referred to in section B.01.311, D.01.006 or D.02.004,
    (iii) a health-related name, statement, logo, symbol, seal of approval or mark, or
    (iv) the phrase "nutrition facts", "valeur nutritive" or "valeurs nutritives".

(4) Subsection (1) does not apply to a formulated liquid diet, a human milk substitute, a food represented as containing a human milk substitute, a meal replacement, a nutritional supplement or a food represented for use in a very low energy diet.

(5) The label of or advertisement for a formulated liquid diet, a human milk substitute, a food represented as containing a human milk substitute, a meal replacement, a nutritional supplement or a food represented for use in a very low energy diet shall not contain a nutrition facts table or the phrase "nutrition facts", "valeur nutritive" or "valeurs nutritives".

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(6) If, for a prepackaged product other than one intended solely for children under two years of age, the information in respect of seven or more of the energy value and nutrients referred to in column 1 of items 2 to 5 and 7 to 13 of the table to this section may be expressed as "0" in the nutrition facts table in accordance with this section, the nutrition facts table need only include the following information:

(a) the serving of stated size;
(b) the energy value;
(c) the amount of fat;
(d) the amount of carbohydrate;
(e) the amount of protein;
(f) the amount of any nutrient that is the subject of a representation referred to in subparagraph (3) (e) (ii);
(g) the amount of any sugar alcohol, vitamin or mineral nutrient added to the prepackaged product, other than iodide added to salt for table or general household use or fluoride added to prepackaged water or ice;
(h) the amount of any vitamin or mineral nutrient that is declared as a component of one of the prepackaged product's ingredients other than flour;
(i) the amount of any nutrient referred to in column 1 of item 4, 5, 7, 8, 10, 11 or 13 of the table to this section that may not be expressed as "0" in the nutrition facts table; and
(j) the statement "Not a significant source of (naming each nutrient that is omitted from the nutrition facts table in accordance with this subsection)" or, if the prepackaged product meets the condition specified in subsection B.01.455(3), the statement "Not a significant source of other nutrients".

(7) Subsection (1) does not apply to a prepackaged product

(a) that is intended solely for use as an ingredient in the manufacture of other prepackaged products intended for sale to a consumer at the retail level or as an ingredient in the preparation of food by a commercial or industrial enterprise or institution; or
(b) that is a multiple-serving ready-to-serve prepackaged product intended solely to be served in a commercial or industrial enterprise or institution.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

TABLE

CORE INFORMATION

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
1	Serving of stated size	"Serving Size (naming the serving size)", "Serving (naming the serving size)" or "Per (naming the serving size)"	(1) The size is expressed in one of the following units: (a) in the case of a food that is usually divided into pieces before being consumed (such as cake, pie and pizza), a fraction of the entire food; (b) in the case of a food described in subsection B.01.002A(2), the entire container; and (c) in all other cases, in a commonly used unit in respect of which the quantity is visibly measurable, such as millilitres, cups, tablespoons or "(naming the unit of food)". (2) The size expressed in accordance with subitem (1) is followed by the size expressed in grams or millilitres, as specified by paragraph B.01.002A(1)(b).	(1) The size when expressed in metric units is rounded off (a) if it is less than 10 g or 10 mL, to the nearest multiple of 0.1 g or 0.1 mL; and (b) if it is 10 g or more or 10 mL or more, to the nearest multiple of 1 g or 1 mL. (2) The size when expressed as a fraction is represented by a numerator and a denominator separated by a line. (3) The size shall include the word "assorted" if the information in the nutrition facts table of a prepackaged product that contains an assortment of foods is set out as a composite value.

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• Coming into force identical for all sections from B.01.400 to B.01.603.

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
2	Energy value	"Calories", "Total Calories" or "Calories, Total"	The value is expressed in Calories per serving of stated size.	The value is rounded off (a) if it is less than 5 Calories (i) if the product meets the conditions set out in column 2 of item 1 of the table following section B.01.513 for the subject "free of energy" set out in column 1, to "0" Calorie, and (ii) in all other cases, to the nearest multiple of 1 Calorie; (b) if it is 5 Calories or more but not more than 50 Calories, to the nearest multiple of 5 Calories; and (c) if it is more than 50 Calories, to the nearest multiple of 10 Calories.
3	Amount of fat	"Fat", "Total Fat" or "Fat, Total"	The amount is expressed (a) in grams per serving of stated size; and (b) as a percentage of the daily value per serving of stated size.	(1) The amount is rounded off (a) if it is less than 0.5 g (i) if the product meets the conditions set out in column 2 of item 11 of the table following section B.01.513 for the subject "free of fat" set out in column 1 and the amounts of saturated fatty acids and *trans* fatty acids are declared as "0 g" in the nutrition facts table or are omitted from that table in accordance with subsection B.01.401 (6) and no other fatty acids are declared in an amount greater than 0 g, to "0 g", and

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*** Coming into force identical for all sections from B.01.400 to B.01.603.**

	Column 1	Column 2	Column 3	Column 4
	Item	Information	Description	Unit	Manner of expression
					(ii) in all other cases, to the nearest multiple of 0.1 g; (b) if it is 0.5 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and (c) if it is more than 5 g, to the nearest multiple of 1 g. (2) The percentage is rounded off (a) if the amount is declared as "0 g", to "0 %"; and (b) in all other cases, to the nearest multiple of 1%.
12-12-02	4	Amount of saturated fatty acids	"Saturated Fat", "Saturated Fatty Acids", "Saturated" or "Saturates"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g (i) if the product meets the conditions set out in column 2 of item 18 of the table following section B.01.513 for the subject "free of saturated fatty acids" set out in column 1, to "0 g", and (ii) in all other cases, to the nearest multiple of 0.1 g; (b) if it is 0.5 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and (c) if it is more than 5 g, to the nearest multiple of 1 g.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
5	Amount of *trans* fatty acids	"Trans Fat", "Trans Fatty Acids" or "Trans"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g (i) if the product meets the conditions set out in column 2 of item 22 of the table following section B.01.513 for the subject "free of *trans* fatty acids" set out in column 1, to "0 g", and (ii) in all other cases, to the nearest multiple of 0.1 g; (b) if it is 0.5 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and (c) if it is more than 5 g, to the nearest multiple of 1 g.
6	The sum of saturated fatty acids and *trans* fatty acids	"Saturated Fat + Trans Fat", "Saturated Fatty Acids + Trans Fatty Acids", "Saturated + Trans" or "Saturates + Trans"	The sum is expressed as a percentage of the daily value per serving of stated size.	The percentage is rounded off (a) if the amounts of saturated fatty acids and *trans* fatty acids are declared as "0 g", to "0 %"; and (b) in all other cases, to the nearest multiple of 1%.

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*** Coming into force identical for all sections from B.01.400 to B.01.603.**

	Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
	7	Amount of cholesterol	"Cholesterol"	The amount is expressed in milligrams per serving of stated size and may also be expressed as a percentage of the daily value per serving of stated size.	(1) The amount is rounded off (a) if the product meets the conditions set out in column 2 of item 27 of the table following section B.01.513 for the subject "free of cholesterol" set out in column 1, to "0 mg"; and (b) in all other cases, to the nearest multiple of 5 mg. (2) The percentage is rounded off (a) if the amount is declared as "0 mg" to "0 %"; and (b) in all other cases, to the nearest multiple of 1%.
12-12-02	8	Amount of sodium	"Sodium"	The amount is expressed (a) in milligrams per serving of stated size; and (b) as a percentage of the daily value per serving of stated size.	(1) The amount is rounded off (a) if it is less than 5 mg (i) if the product meets the conditions set out in column 2 of item 31 of the table following section B.01.513 for the subject "free of sodium or salt" set out in column 1, to "0 mg", and (ii) in all other cases, to the nearest multiple of 1 mg;

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

	Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
					(b) if it is 5 mg or more but not more than 140 mg, to the nearest multiple of 5 mg; and (c) if it is more than 140 mg, to the nearest multiple of 10 mg. (2) The percentage is rounded off (a) if the amount is declared as "0 mg", to "0 %"; and (b) in all other cases, to the nearest multiple of 1%.
12-12-02	9	Amount of carbohydrate	"Carbohydrate", "Total Carbohydrate" or "Carbohydrate, Total"	The amount is expressed (a) in grams per serving of stated size; and (b) as a percentage of the daily value per serving of stated size.	(1) The amount is rounded off (a) if it is less than 0.5 g, to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g. (2) The percentage is rounded off (a) if the amount is declared as "0 g", to "0 %"; and (b) in all other cases, to the nearest multiple of 1%.
	10	Amount of fibre	"Fibre", "Fiber", "Dietary Fibre" or "Dietary Fiber"	The amount is expressed (a) in grams per serving of stated size; and (b) as a percentage of the daily value per serving of stated size.	(1) The amount is rounded off (a) if it is less than 0.5 g, to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g. (2) The percentage is rounded off (a) if the amount is declared as "0 g", to "0 %"; and (b) in all other cases, to the nearest multiple of 1%.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
11	Amount of sugars	"Sugars"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g, to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
12	Amount of protein	"Protein"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g, to the nearest multiple of 0.1 g; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
13	Amount of (a) vitamin A (b) vitamin C (c) calcium (d) iron	(a) "Vitamin A" or "Vit A" (b) "Vitamin C" or "Vit C" (c) "Calcium" (d) "Iron"	The amount is expressed as a percentage of the daily value per serving of stated size.	The percentage is rounded off (a) if it is less than 2% (i) if the product contains less than 1% of the daily value per reference amount and per serving of stated size, to "0 %", and (ii) in all other cases, to "2 %"; (b) if it is 2% or more but not more than 10%, to the nearest multiple of 2%; (c) if it is more than 10% but not more than 50%, to the nearest multiple of 5%; and (d) if it is more than 50%, to the nearest multiple of 10%.

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Additional Information

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***B.01.402.** (1) The nutrition facts table may also contain information set out in column 1 of the table to this section.

(2) If information set out in column 1 of the table to this section is included in the nutrition facts table, it shall be expressed using a description set out in column 2, in the unit set out in column 3 and in the manner set out in column 4.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

(3) The amount of omega-6 polyunsaturated fatty acids, omega-3 polyunsaturated fatty acids and monounsaturated fatty acids shall be in the nutrition facts table if

(a) the amount of any of those groups of fatty acids or the amount of polyunsaturated fatty acids is in the nutrition facts table or is shown on the label of the prepackaged product or in any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product; or

(b) the amount of any specific fatty acid is shown on the label of the prepackaged product or in any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product.

(4) If the label of a prepackaged product, or any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product, contains a representation, express or implied, that includes information that is set out in column 1 of the table to this section, that information shall also be in the nutrition facts table.

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(5) The amount of potassium shall be in the nutrition facts table if the prepackaged product contains added potassium salts and the label of the product or any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product contains a statement or claim referred to in column 4 of any of items 31 to 36 of the table following section B.01.513 for the subject "free of sodium or salt", "low in sodium or salt", "reduced in sodium or salt", "lower in sodium or salt", "no added sodium or salt" or "lightly salted" set out in column 1.

(6) The nutrition facts table shall show the amount of any sugar alcohol, vitamin or mineral nutrient added to the prepackaged product, except in the case of iodide added to salt for table or general household use or fluoride added to prepackaged water or ice.

(7) The nutrition facts table shall show the amount of any vitamin or mineral nutrient that is declared as a component of one of the prepackaged product's ingredients other than flour.

(8) Despite subsection (1) and item 1 of the table to this section, the nutrition facts table shall not include information on servings per container if the serving of stated size is expressed in cups or tablespoons.

(9) If information set out in column 1 of the table to this section is included in the nutrition facts table, it shall be shown

(a) in English and French; or
(b) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the product may be shown in that language only and is shown on the label in that language.

TABLE

ADDITIONAL INFORMATION

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
1	Servings per container	"Servings Per Container" or "(number of units) Per Container"	The quantity is expressed in number of servings.	(1) The quantity is rounded off (a) if it is less than 2, to the nearest multiple of 1; (b) if it is between 2 and 5, to the nearest multiple of 0.5; and (c) if it is more than 5, to the nearest multiple of 1.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
				(2) If a quantity is rounded off, it shall be preceded by the word "about". (3) If the product is of a random weight, the quantity may be declared as "varied".
2	Energy value	"kilojoules" or "kJ"	The value is expressed in kilojoules per serving of stated size.	The value is rounded off to the nearest multiple of 10 kilojoules.
3	Energy value from fat	"Calories from Fat" or "Calories from Total Fat"	The value is expressed in Calories per serving of stated size.	The value is rounded off (a) if it is less than 5 Calories (i) if the amount of fat is declared as "0 g" in the nutrition facts table, to "0" Calorie, and (ii) in all other cases, to the nearest multiple of 1 Calorie; (b) if it is 5 Calories or more but not more than 50 Calories, to the nearest multiple of 5 Calories; and (c) if it is more than 50 Calories, to the nearest multiple of 10 Calories.
4	Energy value from the sum of saturated and *trans* fatty acids	"Calories from Saturated + Trans Fat", "Calories from Saturated + Trans Fatty Acids", "Calories from Saturated + Trans" or "Calories from Saturates + Trans"	The value is expressed in Calories per serving of stated size.	The value is rounded off (a) if it is less than 5 Calories (i) if the amounts of saturated fatty acids and *trans* fatty acids are declared as "0 g" in the nutrition facts table, to "0" Calorie, and (ii) in all other cases, to the nearest multiple of 1 Calorie;

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*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
				(b) if it is 5 Calories or more but not more than 50 Calories, to the nearest multiple of 5 Calories; and (c) if it is more than 50 Calories, to the nearest multiple of 10 Calories.
5	Amount of polyunsaturated fatty acids	"Polyunsaturated Fat", "Polyunsaturated Fatty Acids", "Polyunsaturated" or "Polyunsaturates"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 1 g, to the nearest multiple of 0.1 g; (b) if it is 1 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and (c) if it is more than 5 g, to the nearest multiple of 1 g.
6	Amount of omega-6 polyunsaturated fatty acids	(1) If the nutrition facts table includes the amount of polyunsaturated fatty acids: "Omega-6", "Omega-6 Polyunsaturated Fat", "Omega-6 Polyunsaturated Fatty Acids", "Omega-6 Polyunsaturates" or "Omega-6 Polyunsaturated" (2) In all other cases: "Omega-6 Polyunsaturated Fat", "Omega-6 Polyunsaturated Fatty Acids", "Omega-6 Polyunsaturates" or "Omega-6 Polyunsaturated"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 1 g, to the nearest multiple of 0.1 g; (b) if it is 1 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and (c) if it is more than 5 g, to the nearest multiple of 1 g.
7	Amount of omega-3 polyunsaturated fatty acids	(1) If the nutrition facts table includes the amount of polyunsaturated fatty acids: "Omega-3", "Omega-3 Polyunsaturated Fat", "Omega-3 Polyunsaturated Fatty Acids", "Omega-3 Polyunsaturates" or "Omega-3 Polyunsaturated"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 1 g, to the nearest multiple of 0.1 g; (b) if it is 1 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and (c) if it is more than 5 g, to the nearest multiple of 1 g.

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*** Coming into force identical for all sections from B.01.400 to B.01.603.**

	Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
			(2) In all other cases: "Omega-3 Polyunsaturated Fat", "Omega-3 Polyunsaturated Fatty Acids", "Omega-3 Polyunsaturates", or "Omega-3 Polyunsaturated"		
	8	Amount of monounsaturated fatty acids	"Monounsaturated Fat", "Monounsaturated Fatty Acids", "Monounsaturates" or "Monounsaturated"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 1 g, to the nearest multiple of 0.1 g; (b) if it is 1 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and (c) if it is more than 5 g, to the nearest multiple of 1 g.
12-12-02	9	Amount of potassium	"Potassium"	The amount is expressed (a) in milligrams per serving of stated size; and (b) as a percentage of the daily value per serving of stated size.	(1) The amount is rounded off (a) if it is less than 5 mg (i) if the product contains less than 5 mg of potassium per reference amount and per serving of stated size, to "0 mg", and (ii) in all other cases, to the nearest multiple of 1 mg; (b) if it is 5 mg or more but not more than 140 mg, to the nearest multiple of 5 mg; and (c) if it is more than 140 mg, to the nearest multiple of 10 mg.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
				(2) The percentage is rounded off (a) if the amount is declared as "0 mg", to "0 %"; or (b) in all other cases, to the nearest multiple of 1%.
10	Amount of soluble fibre	"Soluble Fibre" or "Soluble Fiber"	The amount is expressed as grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g, to "0 g", and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
11	Amount of insoluble fibre	"Insoluble Fibre" or "Insoluble Fiber"	The amount is expressed as grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g, to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
12	Amount of sugar alcohol	(1) If the food contains only one type of sugar alcohol: "Sugar Alcohol", "Polyol" or "(naming the sugar alcohol)" (2) In all other cases: "Sugar Alcohols" or "Polyols"	The amount is expressed as grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g, to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
13	Amount of starch	"Starch"	The amount is expressed as grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g, to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.

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*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
14	Amount of		The amount is expressed as a percentage of the daily value per serving of stated size.	The percentage is rounded off (a) if it is less than 2% (i) if the product contains less than 1% of the daily value per reference amount and per serving of stated size, to "0 %", and (ii) in all other cases, to the nearest multiple of 2%; (b) if it is 2% or more but not more than 10%, to the nearest multiple of 2%; (c) if it is more than 10% but not more than 50%, to the nearest multiple of 5%; and (d) if it is more than 50%, to the nearest multiple of 10%.
	(a) vitamin D	(a) "Vitamin D" or "Vit D"		
	(b) vitamin E	(b) "Vitamin E" or "Vit E"		
	(c) vitamin K	(c) "Vitamin K" or "Vit K"		
	(d) thiamine	(d) "Thiamine", "Thiamin", "Thiamine (Vitamin B_1)", "Thiamine (Vit B_1)", "Thiamin (Vitamin B_1)" or "Thiamin (Vit B_1)"		
	(e) riboflavin	(e) "Riboflavin", "Riboflavin (Vitamin B_2)" or "Riboflavin (Vit B_2)"		
	(f) niacin	(f) "Niacin"		
	(g) vitamin B_6	(g) "Vitamin B_6" or "Vit B_6"		
	(h) folate	(h) "Folate"		
	(i) vitamin B_{12}	(i) "Vitamin B_{12}" or "Vit B_{12}"		
	(j) biotin	(j) "Biotin"		
	(k) pantothenic acid	(k) "Pantothenic Acid" or "Pantothenate"		
	(l) phosphorus	(l) "Phosphorus"		
	(m) iodide	(m) "Iodide" or "Iodine"		
	(n) magnesium	(n) "Magnesium"		
	(o) zinc	(o) "Zinc"		
	(p) selenium	(p) "Selenium"		
	(q) copper	(q) "Copper"		
	(r) manganese	(r) "Manganese"		
	(s) chromium	(s) "Chromium"		
	(t) molybdenum	(t) "Molybdenum"		
	(u) chloride	(u) "Chloride"		

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*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
15	Basis of the percent daily values	One of the four footnotes to the subheading "% Daily Value" set out in Figures 18.1(E) and (F) of Schedule L		In the version of the footnote that refers to nutrients, (a) the daily value for potassium is included only if the amount of potassium is declared in the nutrition facts table; and (b) the daily value for cholesterol is included only if the amount of cholesterol is declared in the nutrition facts table as a percentage of the daily value per serving of stated size.
16	Energy conversion factors	"Calories per gram:", "Fat 9", "Carbohydrate 4" and "Protein 4"		

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Foods for Children under Two Years of Age

***B.01.403.** (1) This section applies in respect of a prepackaged product intended solely for children under two years of age.

(2) The nutrition facts table of the product shall not contain

(a) the percentage of the daily value of fat, cholesterol, sodium, potassium, carbohydrate or fibre or of the sum of saturated fatty acids and *trans* fatty acids;

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(b) the energy value from fat or from the sum of saturated fatty acids and *trans* fatty acids; or

(c) any of the footnotes to the subheading "% Daily Value" set out in Figures 18.1(E) and (F) in Schedule L.

(3) The nutrition facts table of the product may omit the amount of saturated fatty acids, *trans* fatty acids and cholesterol.

(4) Despite subsection (3), if the amount of cholesterol is in the nutrition facts table, the amounts of saturated fatty acids and *trans* fatty acids shall also be in the nutrition facts table.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

(5) If the information in respect of six or more of the energy value and nutrients referred to in column 1 of items 2, 3 and 8 to 13 of the table to section B.01.401 may be expressed as "0" in the nutrition facts table of the product in accordance with that section, the nutrition facts table need only include the following information:

(a) the serving of stated size;
(b) the energy value;
(c) the amount of fat;
(d) the amount of carbohydrate;
(e) the amount of protein;
(f) the amount of any nutrient that is the subject of a representation referred to in subparagraph B.01.401 (3) (e) (ii);
(g) the amount of any sugar alcohol, vitamin or mineral nutrient added to the product, other than fluoride added to prepackaged water or ice;
(h) the amount of any vitamin or mineral nutrient that is declared as a component of one of the product's ingredients other than flour;
(i) the amount of any nutrient referred to in column 1 of item 8, 10, 11 or 13 of the table to section B.01.401 that may not be expressed as "0" in the nutrition facts table;
(j) except in the case described in paragraph (k), the statement "Not a significant source of (naming each nutrient that is omitted from the nutrition facts table in accordance with this subsection)", but such a statement may be omitted in respect of saturated fatty acids, *trans* fatty acids and cholesterol; and
(k) if the product meets the condition specified in subsection B.01.462(3), the statement "Not a significant source of other nutrients" or the statement referred to in paragraph (j).

Food for Use in Manufacturing other Foods

***B.01.404.** (1) This section applies to a prepackaged product that is intended solely for use as an ingredient in the manufacture of other prepackaged products intended for sale to a consumer at the retail level or as an ingredient in the preparation of food by a commercial or industrial enterprise or institution.

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(2) No person shall sell the product unless written nutrition information concerning the product accompanies the product when it is delivered to the purchaser.

(3) The nutrition information

(a) shall include the information that would, but for subsection B.01.401(7), be required by sections B.01.401 and B.01.402 to be included in a nutrition facts table for the product;

(b) may include other information that is permitted by section B.01.402 to be included in that nutrition facts table; and

(c) shall be expressed in accordance with sections B.01.401 and B.01.402, subject to the following modifications, namely,
  (i) information for vitamins set out in column I of Table I to Division 1 of Part D and mineral nutrients set out in column I of Table I to Division 2 of that Part shall be expressed in the applicable units referred to in that column,
    (A) per gram or 100 grams of the food, if the net quantity of the food is declared on the label by weight or by count, or
    (B) per millilitre or 100 millilitres of the food, if the net quantity of the food is declared on the label by volume,
  (ii) information for other nutrients and the energy value set out in column 1 of the table to section B.01.401 or in column 1 of the table to section B.01.402 shall be expressed in the units referred to in column 3,
    (A) per gram or 100 grams of the food, if the net quantity of the food is declared on the label by weight of by count, or
    (B) per millilitre or 100 millilitres of the food, if the net quantity of the food is declared on the label by volume,
  (iii) percentages of daily values and information on servings of stated size may be omitted, and
  (iv) the nutrition information shall be stated with a degree of precision that corresponds to the accuracy of the analytical methodology used to produce the information.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Foods for Enterprise or Institution

*** B.01.405.** (1) This section applies to a prepackaged product that is a multiple-serving ready-to-serve prepackaged product intended solely to be served in a commercial or industrial enterprise or institution.

(2) No person shall sell the product unless written nutrition information concerning the product accompanies the product when it is delivered to the purchaser.

(3) The nutrition information

(a) shall include the information that would, but for subsection B.01.401(7), be required by sections B.01.401 and B.01.402 to be included in a nutrition facts table for the product;

(b) may include other information that is permitted by section B.01.402 to be included in that nutrition facts table; and

(c) shall be expressed in accordance with sections B.01.401 and B.01.402.

Basis of Information

***B.01.406.** (1) Subject to subsections (2) to (8), the information in the nutrition facts table shall be set out only on the basis of the prepackaged product as offered for sale.

(2) If a prepackaged product contains separately packaged ingredients or foods that are intended to be consumed together, the information in the nutrition facts table shall be set out for each ingredient or food or for the entire product.

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(3) If a prepackaged product contains an assortment of foods of the same type and the typical serving consists of only one of those foods, the information in the nutrition facts table shall be set out

(a) on the basis of each of the foods contained in the product, if the nutrition information set out in column 1 of the table to section B.01.401 for each of those foods is different; or

(b) on the basis of one of the foods contained in the product, if the nutrition information set out in column 1 of the table to section B.01.401 for each of those foods is the same.

(4) If a prepackaged product contains an assortment of foods of the same type and the typical serving consists of more than one of those foods, the information in the nutrition facts table shall be set out for each of the foods contained in the product or as a composite value.

(5) If a prepackaged product contains a food that is to be prepared in accordance with directions provided in or on the package or that is commonly combined with other ingredients or another food or cooked before being consumed, the nutrition facts table may also set out information for the food as prepared, in which case

(a) the nutrition facts table shall set out the following information for the food as prepared, namely,

(i) except in the case described in subparagraph (ii), the amount of the food expressed in a unit specified in column 3 of paragraph 1(1)(a) or (c) of the table to section B.01.401 as "about (naming the serving size)" or "about (naming the serving size) prepared" and, if applicable, in the manner specified in column 4 of subitems 1(1) and (2),

(ii) if the food is commonly served combined with another food, the amount of the other food expressed in a unit specified in column 3 of paragraph 1(1)(c) of the table to section B.01.401 and, if applicable, in the manner specified in column 4 of subitem 1(1),

(iii) the energy value, expressed using a description set out in column 2 of item 2 of the table to section B.01.401, in the unit set out in column 3 and in the manner set out in column 4,

(iv) if it is declared in the nutrition facts table for the food as sold, the energy value from fat, expressed using a description set out in column 2 of item 3 of the table to section B.01.402, in the unit set out in column 3 and in the manner set out in column 4, and

(v) the information set out in column 1 of items 3, 6 to 10 and 13 of the table to section B.01.401 and in column 1 of items 9 and 14 of the table to section B.01.402 that is declared as a percentage of the daily value in the nutrition facts table for the food as sold, expressed using a description set out in column 2, as a percentage of the daily value per serving of stated size and in the manner specified in column 4; and

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

(b) the nutrition facts table may also set out the following information for the added ingredients or the other food, if it is declared in the nutrition facts table for the food as sold, namely,

(i) the information set out in column 1 of items 3 to 5 and 7 to 12 of the table to section B.01.401, expressed using a description set out in column 2, in milligrams for the information set out in column 1 of items 7 and 8 and in grams for the information set out in column 1 of items 3 to 5 and 9 to 12 and in the manner specified in column 4, and

(ii) the information set out in column 1 of items 5 to 13 of the table to section B.01.402, expressed using a description set out in column 2, in milligrams for the information set out in column 1 of item 9 and in grams for the information set out in column 1 of items 5 to 8 and 10 to 13 and in the manner specified in column 4.

(6) Subsection (5) does not apply in respect of a prepackaged product that is intended solely for children under two years of age.

(7) Subject to subsection (8), the information in the nutrition facts table may also be set out on the basis of other amounts of a food that reflect different uses or different units of measurement of a food, in which case

(a) the nutrition facts table shall set out the following information for each of the other amounts of food, namely,

(i) the amount of the food expressed in a unit specified in column 3 of subitem 1(1) of the table to section B.01.401 and, if applicable, in the manner specified in column 4 of subitems 1(1) and (2),

(ii) the energy value, expressed using a description set out in column 2 of item 2 of the table to section B.01.401, in the unit set out in column 3 and in the manner set out in column 4,

(iii) if it is declared in the nutrition facts table for the first amount of food for which information is declared, the energy value from fat, expressed using a description set out in column 2 of item 3 of the table to section B.01.402, in the unit set out in column 3 and in the manner set out in column 4, and

(iv) the information set out in column 1 of items 3, 6 to 10 and 13 of the table to section B.01.401 and in column 1 of items 9 and 14 of the table to section B.01.402 that is declared as a percentage of the daily value in the nutrition facts table for the first amount of food for which information is declared, expressed using a description set out in column 2, as a percentage of the daily value per serving of stated size and in the manner specified in column 4;

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(b) if the nutrition facts table is set out in a version of the dual format specified in section B.01.458, it may also set out the amount of each of the other amounts of food expressed in the unit specified in column 3 of subitem 1(2) of the table to section B.01.401 and in the manner specified in column 4 of subitem 1(1), if that information is declared in the nutrition facts table for the first amount of food for which information is declared; and

(c) if the nutrition facts table is set out in a version of the aggregate format specified in section B.01.459 or B.01.464, it shall also set out the following information for each of the other amounts of food, if that information is declared in the nutrition facts table for the first amount of food for which information is declared, namely,

(i) the amount of the food expressed in the unit specified in column 3 of subitem 1(2) of the table to section B.01.401 and in the manner specified in column 4 of subitem 1(1),

(ii) the information set out in column 1 of items 3 to 5 and 7 to 12 of the table to section B.01.401, expressed using a description set out in column 2, in milligrams for the information set out in column 1 of items 7 and 8 and in grams for the information set out in column 1 of items 3 to 5 and 9 to 12 and in the manner specified in column 4, and

(iii) the information set out in column 1 of items 5 to 13 of the table to section B.01.402, expressed using a description set out in column 2, in milligrams for the information set out in column 1 of item 9 and in grams for the information set out in column 1 of items 5 to 8 and 10 to 13 and in the manner specified in column 4.

(8) If the nutrition facts table of a prepackaged product that is intended solely for children under two years of age sets out information in accordance with subsection (7), it shall set out the information referred to in paragraphs (7) (a) and (c).

[**B.01.407** to **B.01.449** reserved]

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Presentation of Nutrition Facts Table

***B.01.450.** (1) Subject to subsections (2) to (6), the nutrition facts table shall be presented in accordance with the format specified in the applicable figure in Schedule L, having regard to matters such as order of presentation, dimensions, spacing and the use of upper and lower case letters and bold type.

(2) The characters and rules in the nutrition facts table shall be displayed in a single colour that is a visual equivalent of 100% solid black type on a white background or on a uniform neutral background with a maximum 5% tint of colour.

(3) The characters in the nutrition facts table

(a) shall be displayed in a single standard sans serif font that is not decorative and in such a manner that the characters never touch each other or the rules; and

(b) may be displayed with larger dimensions than those specified in the applicable figure in Schedule L if all the characters in the table are enlarged in a uniform manner.

(4) A rule that is specified in the applicable figure in Schedule L as being a 1 point rule or a 2 point rule may be displayed with larger dimensions in the nutrition facts table.

(5) The information in the nutrition facts table shall be in accordance with sections B.01.400 to B.01.403 and B.01.406.

(6) In a nutrition facts table consisting of a table in both English and French, the order of languages may be reversed from the order shown in the applicable figure in Schedule L.

Location of Nutrition Facts Table

***B.01.451.** (1) Subject to subsection (2), the nutrition facts table shall be displayed on the label of the prepackaged product

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(a) in a table in English and a table in French on the same continuous surface of the available display surface;
(b) in a table in both English and French on a continuous surface of the available display surface; or
(c) in a table in English on a continuous surface of the available display surface and a table in French on another continuous surface of the available display surface that is of the same size and prominence as the first surface.

(2) If in accordance with subsection B.01.012(3) or (7) the information required by these Regulations may be shown on the label of a prepackaged product in English only or in French only and is shown in that language, the nutrition facts table may be displayed on the label of the prepackaged product in a table in that language only on a continuous surface of the available display surface.

Orientation of Nutrition Facts Table

***B.01.452.** (1) Subject to subsection (2), the nutrition facts table shall be oriented in the same manner as other information appearing on the label of the prepackaged product.

(2) If a version of a nutrition facts table cannot be oriented in the same manner as other information appearing on the label of the prepackaged product, it shall be oriented in another manner if there is sufficient space to do so and the food contained in the package does not leak out and is not damaged when the package is turned over.

(3) Subsection (1) does not apply in respect of a nutrition facts table that is set out on the top or bottom of a prepackaged product.

Application

***B.01.453.** (1) Sections B.01.454 to B.01.460 apply to prepackaged products other than those that are intended solely for children under two years of age.

(2) Sections B.01.461 to B.01.465 apply to prepackaged products that are intended solely for children under two years of age.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

* **B.01.454.** (1) This section applies to a prepackaged product unless any of sections B.01.455 to B.01.459 applies to the product.

(2) Subject to subsection (3), the nutrition facts table of the prepackaged product shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(3) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(a) the bilingual standard format in accordance with Figure 3.5(B), 3.6(B) or 3.7(B) of Schedule L;

(b) the bilingual horizontal format in accordance with Figure 4.3(B), 4.4(B) or 4.5(B) of Schedule L;

(c) the linear format in accordance with Figures 16.1(E) and (F) or 16.2(E) and (F) of Schedule L;

12-12-02 (d) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table; or

(e) a manner described in section B.01.466.

(4) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included in that table.

(5) Despite subsections (2) and (3), if the prepackaged product is sold only in the retail establishment where the product is packaged, is labelled by means of a sticker and has an available display surface of 200 cm^2 or more, its nutrition facts table shall be set out in a version that is listed in column 1 of items 1 to 3 of Parts 1 to 3 of the table to this section, without regard to any condition specified in column 2.

(6) Despite subsections (2) and (3), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (3)(a), (b) or (c) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

* **Coming into force identical for all sections from B.01.400 to B.01.603.**

TABLE

PART 1
STANDARD FORMAT

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	1.1 (E) and (F) (8 point type with 12 point leading)	
2	1.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	1.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	1.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	1.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	1.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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PART 2
NARROW STANDARD FORMAT

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	2.1 (E) and (F) (8 point type with 12 point leading)	
2	2.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	2.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	2.4 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

PART 3
BILINGUAL STANDARD FORMAT

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	3.1 (B) (8 point type with 12 point leading)	
2	3.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	3.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	3.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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PART 4
BILINGUAL HORIZONTAL FORMAT

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	4.1 (B) (7 point condensed type with 11 point leading)	The versions in Parts 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
2	4.2 (B) (6 point condensed type with 10 point leading)	The versions in Parts 1 to 3 and in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

Simplified Formats

***B.01.455.** (1) This section applies to a prepackaged product if it satisfies the condition set out in subsection B.01.401(6) and its nutrition facts table includes only the information referred to in paragraphs B.01.401 (6) (a) to (j).

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(2) Subject to subsection (3), the nutrition facts table of the prepackaged product shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(3) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table containing only the information referred to in paragraphs B.01.401(6) (a) to (j) in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

(a) the bilingual simplified standard format in accordance with Figure 6.5 (B) or 6.6 (B) of Schedule L;

(b) the bilingual simplified horizontal format in accordance with Figure 7.3 (B) or 7.4 (B) of Schedule L;

(c) the simplified linear format in accordance with Figures 17.1 (E) and (F) or 17.2(E) and (F) of Schedule L;

(d) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table; or

(e) a manner described in section B.01.466.

(4) Despite subsections (2) and (3), if the prepackaged product is sold only in the retail establishment where the product is packaged, is labelled by means of a sticker and has an available display surface of 200 cm^2 or more, its nutrition facts table shall be set out in a version that is listed in column 1 of items 1 to 3 of Parts 1 and 2 of the table to this section, without regard to any condition specified in column 2.

(5) Despite subsections (2) and (3), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (3) (a), (b) or (c) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

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TABLE

PART 1
SIMPLIFIED STANDARD FORMAT

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	5.1 (E) and (F) (8 point type with 12 point leading)	
2	5.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	5.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	5.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	5.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	5.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

PART 2
BILINGUAL SIMPLIFIED STANDARD FORMAT

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	6.1 (B) (8 point type with 12 point leading)	
2	6.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	6.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	6.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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PART 3
BILINGUAL SIMPLIFIED HORIZONTAL FORMAT

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	7.1 (B) (7 point condensed type with 11 point leading)	The versions in Parts 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
2	7.2 (B) (6 point condensed type with 10 point leading)	The versions in Parts 1 and 2 and in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

Dual Format – Foods Requiring Preparation

* **B.01.456.** (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product includes information referred to in subsection B.01.406(5), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(a) the bilingual dual format in accordance with Figure 9.5(B) or 9.6(B) of Schedule L; or

(b) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included in the table, together with the information referred to in subsection B.01.406(5).

* **Coming into force identical for all sections from B.01.400 to B.01.603.**

(4) Despite subsections (1) and (2), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (2) (a) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

TABLE

PART 1
DUAL FORMAT – FOODS REQUIRING PREPARATION

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	8.1 (E) and (F) (8 point type with 12 point leading)	
2	8.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	8.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	8.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	8.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	8.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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*** Coming into force identical for all sections from B.01.400 to B.01.603.**

PART 2
BILINGUAL DUAL FORMAT – FOODS REQUIRING PREPARATION

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	9.1 (B) (8 point type with 12 point leading)	
2	9.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	9.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	9.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

Aggregate Format – Different Kinds of Foods

***B.01.457.** (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product includes separate information for each food or ingredient as provided in subsection B.01.406(2), paragraph B.01.406(3)(a) or subsection B.01.406(4), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

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(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out

(a) in the case of a product described in subsection B.01.406 (2) or (4), in
  (i) the bilingual aggregate format in accordance with Figure 11.5(B) or 11.6(B) of Schedule L, or
  (ii) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table, or

(b) in the case of a product described in paragraph B.01.406(3) (a), in
  (i) the bilingual aggregate format in accordance with Figure 11.5(B) or 11.6(B) of Schedule L,
  (ii) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table, or
  (iii) a manner described in section B.01.466.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each food or ingredient for which separate information is set out in the table.

(4) Despite subsections (1) and (2), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in subparagraph (2)(a)(i) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

TABLE

PART 1
AGGREGATE FORMAT – DIFFERENT KINDS OF FOODS

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	10.1 (E) and (F) (8 point type with 12 point leading)	
2	10.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	10.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	10.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	10.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	10.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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PART 2
BILINGUAL AGGREGATE FORMAT – DIFFERENT KINDS OF FOODS

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	11.1 (B) (8 point type with 12 point leading)	
2	11.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	11.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	11.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Dual Format – Different Amounts of Food

***B.01.458.** (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product includes separate information for different amounts of the food as provided in paragraph B.01.406(7)(a) without including the information referred to in paragraph B.01.406(7)(c), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

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(a) the bilingual dual format in accordance with Figure 13.5(B) or 13.6(B) of Schedule L; or

(b) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each amount of the food for which separate information is set out in the table.

(4) Despite subsections (1) and (2), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (2) (a) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

TABLE

PART 1
DUAL FORMAT – DIFFERENT AMOUNTS OF FOOD

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	12.1 (E) and (F) (8 point type with 12 point leading)	
2	12.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	12.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	12.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	12.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	12.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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*** Coming into force identical for all sections from B.01.400 to B.01.603.**

PART 2
BILINGUAL DUAL FORMAT – DIFFERENT AMOUNTS OF FOOD

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	13.1 (B) (8 point type with 12 point leading)	
2	13.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	13.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	13.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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Aggregate Format – Different Amounts of Food

***B.01.459.** (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product includes separate information for different amounts of the food as provided in paragraphs B.01.406(7)(a) and (c), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(a) the bilingual aggregate format in accordance with Figure 15.5(B) or 15.6(B) of Schedule L; or

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(b) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each amount of the food for which separate information is set out in the table.

(4) Despite subsections (1) and (2), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental containter or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (2) (a) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

TABLE

PART 1
AGGREGATE FORMAT – DIFFERENT AMOUNTS OF FOOD

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	14.1 (E) and (F) (8 point type with 12 point leading)	
2	14.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	14.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	14.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	14.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	14.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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PART 2
BILINGUAL AGGREGATE FORMAT – DIFFERENT AMOUNTS OF FOOD

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	15.1 (B) (8 point type with 12 point leading)	
2	15.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	15.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	15.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Presentation of Additional Information

***B.01.460.** (1) If information referred to in column 1 of the table to section B.01.402 is included in a nutrition facts table that is set out in a version consisting of a table in English and a table in French or a table in English or French, that information shall be displayed

(a) in accordance with the order of presentation, the use of indents and the presentation of footnotes illustrated in Figures 18.1 (E) and (F) of Schedule L; and

(b) in respect of matters other than those referred to in paragraph (a), in accordance with the format that is specified in the applicable figure in Schedule L.

(2) If information referred to in column 1 of the table to section B.01.402 is included in a nutrition facts table that is set out in a version consisting of a table in both English and French, that information shall be displayed

(a) in accordance with the order of presentation, the use of indents and the presentation of footnotes illustrated in Figure 19.1 (B) of Schedule L; and

(b) in respect of matters other than those referred to in paragraph (a), in accordance with the format that is specified in the applicable figure in Schedule L.

(3) Despite paragraph (1)(a), the use of indents illustrated in Figures 18.1(E) and (F) of Schedule L is not applicable if information referred to in column 1 of the table to section B.01.402 is set out in the linear format referred to in paragraph B.01.454(3)(c) or the simplified linear format referred to in paragraph B.01.455 (3)(c).

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Standard and Horizontal Formats – Children under Two Years of Age

***B.01.461.** (1) This section applies to a prepackaged product that is intended solely for children under two years of age unless section B.01.462, B.01.463 or B.01.464 applies to the product.

(2) Subject to subsection (3), the nutrition facts table of the prepackaged product shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(3) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(a) the bilingual standard format in accordance with Figure 22.5(B), 22.6(B) or 22.7(B) of Schedule L;

(b) the bilingual horizontal format in accordance with Figure 23.3(B) or 23.4(B) of Schedule L;

(c) the linear format in accordance with Figures 31.1(E) and (F) or 31.2(E) and (F) of Schedule L;

(d) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table; or

(e) a manner described in Section B.01.466.

(4) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included in that table.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

TABLE

PART 1
STANDARD FORMAT – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	20.1 (E) and (F) (8 point type with 12 point leading)	
2	20.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	20.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	20.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	20.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	20.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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PART 2
NARROW STANDARD FORMAT – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	21.1 (E) and (F) (8 point type with 12 point leading)	
2	21.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	21.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	21.4 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

PART 3
BILINGUAL STANDARD FORMAT – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	22.1 (B) (8 point type with 12 point leading)	
2	22.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	22.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	22.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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PART 4
BILINGUAL HORIZONTAL FORMAT – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	23.1 (B) (7 point condensed type with 11 point leading)	The versions in Parts 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
2	23.2 (B) (6 point condensed type with 10 point leading)	The versions in Parts 1 to 3 and in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

Simplified Formats – Children under Two Years of Age

***B.01.462.** (1) This section applies to a prepackaged product that is intended solely for children under two years of age if it satisfies the condition set out in subsection B.01.403(5) and its nutrition facts table includes only the information referred to in paragraphs B.01.403(5)(a) to (k).

(2) Subject to subsection (3), the nutrition facts table of the prepackaged product shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

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(3) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table containing only the information referred to in paragraphs B.01.403(5) (a) to (k) in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(a) the bilingual simplified standard format in accordance with Figure 25.5(B) or 25.6(B) of Schedule L;

(b) the bilingual simplified horizontal format in accordance with Figure 26.3(B) or 26.4(B) of Schedule L;

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

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(c) the simplified linear format in accordance with Figures 32.1(E) and (F) or 32.2 (E) and (F) of Schedule L;

(d) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table; or

(e) a manner described in section B.01.466.

TABLE

PART 1
SIMPLIFIED STANDARD FORMAT – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	24.1 (E) and (F) (8 point type with 12 point leading)	
2	24.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	24.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	24.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	24.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	24.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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*** Coming into force identical for all sections from B.01.400 to B.01.603.**

PART 2

BILINGUAL SIMPLIFIED STANDARD FORMAT – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	25.1 (B) (8 point type with 12 point leading)	
2	25.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	25.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	25.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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PART 3

BILINGUAL SIMPLIFIED HORIZONTAL FORMAT – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	26.1 (B) (7 point condensed type with 11 point leading)	The versions in Parts 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
2	26.2 (B) (6 point condensed type with 10 point leading)	The versions in Parts 1 and 2 and in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

Aggregate Format – Different Kinds of Foods – Children under Two Years of Age

***B.01.463.** (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product that is intended solely for children under two years of age includes separate information for each food or ingredient as provided in subsection B.01.406(2), paragraph B.01.406(3)(a) or subsection B.01.406(4), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

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(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out

(a) in the case of a product described in subsection B.01.406(2) or (4), in
  (i) the bilingual aggregate format in accordance with Figure 28.5(B) or 28.6(B) of Schedule L, or
  (ii) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table, or

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

(b) in the case of a product described in paragraph B.01.406(3) (a), in

(i) the bilingual aggregate format in accordance with Figure 28.5(B) or 28.6(B) of Schedule L,

12-12-02 (ii) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table, or

(iii) a manner described in section B.01.466.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each food or ingredient for which separate information is set out in the table.

TABLE

PART 1
AGGREGATE FORMAT – DIFFERENT KINDS OF FOODS – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	27.1 (E) and (F) (8 point type with 12 point leading)	
2	27.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	27.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
12-12-02 4	27.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	27.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	27.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

BILINGUAL AGGREGATE FORMAT – DIFFERENT KINDS OF FOODS – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	28.1 (B) (8 point type with 12 point leading)	
2	28.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	28.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	28.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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Aggregate Format – Different Amounts of Food – Children under Two Years of Age

***B.01.464.** (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product that is intended solely for children under two years of age includes separate information for different amounts of the food as provided in subsection B.01.406(8), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

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(a) the bilingual aggregate format in accordance with Figure 30.5(B) or 30.6(B) of Schedule L; or
(b) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each amount of the food for which separate information is set out in the table.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

TABLE

PART 1
AGGREGATE FORMAT – DIFFERENT AMOUNTS OF FOOD – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	29.1 (E) and (F) (8 point type with 12 point leading)	
2	29.2 (E) and (F) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	29.3 (E) and (F) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	29.4 (E) and (F) (7 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
5	29.5 (E) and (F) (6 point condensed type with 10 point leading)	The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
6	29.6 (E) and (F) (6 point condensed type with 9 point leading)	The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

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PART 2
BILINGUAL AGGREGATE FORMAT – DIFFERENT AMOUNTS OF FOOD – CHILDREN UNDER TWO YEARS OF AGE

Item	Column 1 Figure in Schedule L (Version)	Column 2 Condition of use
1	30.1 (B) (8 point type with 12 point leading)	
2	30.2 (B) (7 point type with 11 point leading)	The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
3	30.3 (B) (7 point condensed type with 11 point leading)	The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.
4	30.4 (B) (6 point condensed type with 10 point leading)	The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Presentation of Additional Information – Children under Two Years of Age

***B.01.465.** (1) This section applies to a prepackaged product that is intended solely for children under two years of age.

(2) If information referred to in column 1 of the table to section B.01.402 in included in a nutrition facts table that is set out in a version consisting of a table in English and a table in French or a table in English or French, that information shall be displayed

(a) in accordance with the order of presentation and the use of indents illustrated in Figures 33.1(E) and (F) of Schedule L; and
(b) in respect of matters other than those referred to in paragraph (a), in accordance with the format that is specified in the applicable figure in Schedule L.

(3) If information referred to in column 1 of the table to section B.01.402 is included in a nutrition facts table that is set out in a version consisting of a table in both English and French, that information shall be displayed

(a) in accordance with the order of presentation and the use of indents illustrated in Figure 34.1(B) of Schedule L; and
(b) in respect of matters other than those referred to in paragraph (a), in accordance with the format that is specified in the applicable figure in Schedule L.

(4) Despite paragraph (2)(a), the use of indents illustrated in Figures 33.1(E) and (F) of Schedule L is not applicable if information referred to in column 1 of the table to section B.01.402 is set out in the linear format referred to in paragraph B.01.461(3)(c) or the simplified linear format referred to in paragraph B.01.462(3)(c).

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Alternative Methods of Presentation

***B.01.466.** (1) Despite section A.01.016, the nutrition facts table of a prepackaged product that meets the condition specified in subsection B.01.454(3) or B.01.455(3), paragraph B.01.457(2)(b), subsection B.01.461(3) or B.01.462(3) or paragraph B.01.463(2)(b) may be set out on

(a) a tag attached to the package;
(b) a package insert;
(c) the inner side of a label;
(d) a fold-out label; or
(e) an outer sleeve, overwrap or collar.

(2) If the nutrition facts table is set out in a manner described in paragraph (1)(b) or (c), the outer side of the label of the package shall indicate in a type size of not less than 8 points where the nutrition facts table is located.

(3) If the nutrition facts table is set out in a manner described in subsection (1), it shall be set out

(a) in the case of a product described in subsection B.01.454(3), in a version that is described in paragraph B.01.454(3)(a), (b) or (c) or that is listed in column 1 of the table to section B.01.454;
(b) in the case of a product described in subsection B.01.455(3), in a version that is described in paragraph B.01.455(3)(a), (b) or (c) or that is listed in column 1 of the table to section B.01.455;
(c) in the case of a product described in paragraph B.01.457(2)(b), in a version that is described in subparagraph B.01.457(2)(b)(i) or that is listed in column 1 of the table to section B.01.457;
(d) in the case of a product described in subsection B.01.461(3), in a version that is described in paragraph B.01.461(3)(a), (b) or (c) or that is listed in column 1 of the table to section B.01.461;
(e) in the case of a product described in subsection B.01.462(3), in a version that is described in paragraph B.01.462(3)(a), (b) or (c) or that is listed in column 1 of the table to section B.01.462; and
(f) in the case of a product described in paragraph B.01.463(2)(b), in a version that is described in subparagraph B.01.463(2)(b)(i) or that is listed in column 1 of the table to section B.01.463.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Small Packages

***B.01.467.** (1) Despite section A.01.016 and subject to subsection (2), if the available display surface of a prepackaged product is less than 100 cm^2, the label of the product need not carry a nutrition facts table if the outer side of the label contains an indication of how a purchaser or consumer may obtain the nutrition information that would otherwise be required to be set out in a nutrition facts table on the label of the product.

(2) Subsection (1) does not apply to a prepackaged product that is

(a) described in paragraph B.01.401(3)(a), (b), (c) or (e); or
(b) contained in a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase.

(3) An indication referred to in subsection (1)

(a) shall be set out in a type size of not less than 8 points;
(b) shall include a postal address or a toll-free telephone number; and
12-12-02 (c) shall be
  (i) in English and French, or
  (ii) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the product may be shown in that language only and is shown on the label in that language.

(4) The manufacturer of the prepackaged product shall provide the information referred to in subsection (1) to a purchaser or consumer on request

(a) without charge;
(b) in the following manner, namely,
  (i) in the official language in which the information is requested or, if specified by the purchaser or consumer, in both official languages, or
  (ii) in one of the official languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the product may be shown in that language only and is shown on the label in that language; and
(c) in the form of a nutrition facts table that is set out
  (i) in a format, other than a horizontal format, that is specified in any of sections B.01.454 to B.01.459 or B.01.461 to B.01.464 and that would otherwise be carried on the label of the product in accordance with these Regulations, and
  (ii) in a version of that format that is listed in column 1 of item 1 of any Part of the table to the applicable section referred to in subparagraph (i).

(5) In this section, "official languages" means the English language and the French language.

[**B.01.468** to **B.01.499** reserved]

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Nutrient Content Claims

Interpretation

***B.01.500.** (1) The following definitions apply in this section and in the table following section B.01.513.

"combination foods" means the category of food to which belong foods that contain as ingredients foods from more than one food group, or foods from one or more food groups mixed with foods from the category of other foods, such as pizza or lasagna. (*aliments composés*)
"food group" means one of the following categories of foods:
(a) milk products, and milk product alternatives such as fortified plant-based beverages;
(b) meat, poultry and fish, and alternatives such as legumes, eggs, tofu or peanut butter;
(c) bread and grain products; or
(d) vegetables and fruit. (*groupe alimentaire*)
"other foods" means the category of food to which belong foods that are not part of any food group, including
(a) foods that are mostly fats, such as butter, margarine, oil or lard;
(b) foods that are mostly sugars, such as jam, honey, syrup or confectionery;
(c) snack foods, such as potato chips or pretzels;
(d) beverages, such as water, tea, coffee or soft drinks; and
(e) herbs, spices and condiments, such as pickles, mustard or ketchup. (*autres aliments*)
"reference food of the same food group" means a food that can be substituted in the diet for the food to which it is compared and that belongs to
(a) the same food group as the food to which it is compared, such as cheese as a reference food for milk, or chicken as a reference food for tofu;
(b) the category of other foods, if the food to which it is compared also belongs to that category, such as pretzels as a reference food for potato chips; or
(c) the category of combination foods, if the food to which it is compared also belongs to that category, such as pizza as a reference food for lasagna. (*aliment de référence du même groupe alimentaire*)

12-12-02 "similar reference food" means a food of the same type as the food to which it is compared and that has not been processed, formulated, reformulated or otherwise modified in a manner that increases or decreases the energy value or the amount of a nutrient that is the subject of the comparison, such as whole milk as a similar reference food for partly skimmed milk or regular chocolate chip cookies as a similar reference food for fat-reduced chocolate chip cookies. (*aliment de référence similaire*)

(2) The similar reference food referred to in column 3 of item 45 of the table following section B.01.513, with respect to the subject "light in energy or fat" set out in column 1, shall have a nutrient value that is representative of foods of that type that have not been processed, formulated, reformulated or otherwise modified in a manner that increases the energy value or the amount of fat.

Languages

***B.01.501.** The representations provided for in sections B.01.503 to B.01.513 that appear on the label of a food shall be

(a) in English and French; or
(b) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

Statements or Claims

***B.01.502.** (1) No person shall, on the label of or in any advertisement for a food, make a representation, express or implied, that characterizes the energy value of the food or the amount of a nutrient contained in the food.

(2) Subsection (1) does not apply to

(a) a representation otherwise provided for in these Regulations;
(b) a representation provided for by section 35 of the *Processed Products Regulations*;
(c) a representation provided for by subsection 94(4) of the *Meat Inspection Regulations, 1990*;
(d) a representation that characterizes the amount of lactose in a food;
(e) a representation that characterizes the addition of salt to a food, other than any statement or claim set out in column 4 of the table following section B.01.513;

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(f) a representation that characterizes the addition of sugars to a food, other than any statement or claim set out in column 4 of the table following section B.01.513;
(g) a representation that characterizes the amount of starch in a food, if the food is intended solely for children under two years of age;
(h) the representations "defatted (naming the food)", "demineralized (naming the food)" and "high (naming the monosaccharide or disaccharide) (naming the syrup)";
(i) a representation that characterizes the amount of a fatty acid in a vegetable oil and forms part of its common name;
(j) a representation that characterizes the amount of alcohol in beverages that contain more than 0.5% alcohol;
(k) the representation "light salted" with respect to fish; or
(l) the English representation "lean" with respect to a prepackaged meal represented for use in a weight reduction diet or a weight maintenance diet.

***B.01.503.** (1) A person may, on the label of or in any advertisement for a food, make a statement or claim set out in column 4 of the table following section B.01.513, with respect to a subject set out in column 1, if

(a) the food meets the applicable conditions set out in column 2;
(b) the label or advertisement meets the conditions, if any, set out in column 3, in accordance with sections B.01.504 to B.01.506; and
(c) in the case of a food that is not a prepackaged product, or a prepackaged product for which an advertisement is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement includes, per serving of stated size, and in accordance with section B.01.505 or B.01.506 if applicable,
(i) the declaration of the energy value, if the energy value is the subject of the statement or claim, or
(ii) the amount of the nutrient, if a nutrient is the subject of the statement or claim.

(2) Despite subsection (1), no person shall, on the label of or in any advertisement for a food that is intended solely for children under two years of age, make a statement or claim set out in column 4 of the table following section B.01.513, unless it is a statement or claim respecting one of the following subjects set out in column 1:
(a) "source of protein", set out in item 8;
(b) "excellent source of protein", set out in item 9;
(c) "more protein", set out in item 10;
(d) "no added sodium or salt", set out it item 35; or
(e) "no added sugars", set out in item 40.

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(3) If a statement or claim set out in column 4 of the table following section B.01.513 is made on the label of or in any advertisement for a food, all the words, numbers, signs or symbols that constitute the statement or claim shall be of the same size and prominence.

(4) In the English version of the statements or claims, the word "fibre" may be spelled as "fiber".

***B.01.504.** If a statement or claim set out in column 4 of the table following section B.01.513 is made on the label of a food, the information required under the conditions set out in column 3 shall be

(a) adjacent to, without any intervening printed, written or graphic material,
(i) the statement or claim, if the statement or claim is made only once, or
(ii) the most prominent statement or claim on the principal display panel or, if none appears there, the most prominent statement or claim elsewhere on the label, if the statement or claim is made more than once; and
(b) shown in letters of at least the same size and prominence as
(i) those of the statement or claim, if the statement or claim is made only once, or
(ii) those of the most prominent statement or claim on the principal display panel or, if none appears there, the most prominent statement or claim elsewhere on the label, if the statement or claim is made more than once.

***B.01.505.** If a statement or claim set out in column 4 of the table following section B.01.513 is made in an advertisement for a food, other than a radio or television advertisement, the information required under the conditions set out in column 3 and, if applicable, the information required by paragraph B.01.503(1)(c), shall be

(a) adjacent to, without any intervening printed, written or graphic materical, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and
(b) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

***B.01.506.** (1) If a statement or claim set out in column 4 of the table following section B.01.513 is made in a radio or television advertisement, the information required under the conditions set out in column 3 and, if applicable, the information required by paragraph B.01.503(1)(c), shall be provided in the advertisement, except for the information required under the condition set out in paragraph (a) of column 3, in respect of the following subjects set out in column 1, which may be on the label:

(a) "reduced in energy", set out in item 3;
(b) "reduced in fat", set out in item 13;
(c) "reduced in saturated fatty acids", set out in item 20;
(d) "reduced in *trans* fatty acids", set out in item 23;
(e) "reduced in cholesterol", set out in item 29;
(f) "reduced in sodium or salt", set out in item 33;
(g) "lightly salted", set out in item 36;
(h) "reduced in sugars", set out in item 38; and
(i) "light in energy or fat", set out in item 45.

(2) Despite subsection (1), if the statement or claim is made in a radio or television advertisement that is not made or placed by or on the direction of the manufacturer of the food, the information required under the condition set out in paragraph (a) of column 3 of the table following section B.01.513, in respect of the subjects set out in paragraphs (1)(a) to (i), shall be provided in the advertisement.

(3) If the information required under the conditions set out in column 3 of the table following section B.01.513 and the information required by paragraph B.01.503(1)(c) is provided in a radio advertisement or in the audio portion of a television advertisement, that information shall immediately precede or follow the statement or claim.

(4) In the case of a television advertisement, the information required under the conditions set out in column 3 of the table following section B.01.513 and, if applicable, the information required by paragraph B.01.503(1)(c), shall be communicated

(a) in the audio mode, if the statement or claim is made only in the audio portion of the advertisement or in both the audio and visual portions; or
(b) in the audio or visual mode, if the statement or claim is made only in the visual portion of the advertisement.

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(5) If the information required under the conditions set out in column 3 of the table following section B.01.513 and the information required by paragraph B.01.503(1)(c) is communicated in the visual mode of a television advertisement, it shall

(a) appear concurrently with and for at least the same amount of time as the statement or claim;
(b) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and
(c) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

***B.01.507.** A person may, on the label of or in any advertisement for a food, make a representation, express or implied, that the food is for use in an energy-reduced diet, if a statement or claim set out in column 4 of the table following section B.01.513, in respect of any of the following subjects set out in column 1, is made on the label of or in the advertisement for the food, in accordance with section B.01.503:

(a) "free of energy", set out in item 1;
(b) "low in energy", set out in item 2;
(c) "reduced in energy", set out in item 3;
(d) "lower in energy", set out in item 4; or
(e) "free of sugars", set out in item 37.

***B.01.508.** A person may, on the label of or in any advertisement for a food, make a representation, express or implied, that the food is for use in a sodium-restricted diet, if a statement or claim set out in column 4 of the table following section B.01.513, in respect of any of the following subjects set out in column 1, is made on the label of or in the advertisement for the food, in accordance with section B.01.503:

(a) "free of sodium or salt", set out in item 31;
(b) "low in sodium or salt", set out in item 32;
(c) "reduced in sodium or salt", set out in item 33; or
(d) "lower in sodium or salt", set out in item 34.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

***B.01.509.** A person may, on the label of or in any advertisement for a food, make the statement or claim that the food is "unsweetened" if the food meets the conditions set out in column 2 of item 40 of the table following section B.01.513 for the subject "no added sugars" set out in column 1 and the food does not contain a sweetener set out in column I of Table IX to section B.16.100.

***B.01.510.** A statement or claim set out in column 4 of the table following section B.01.513, respecting the following subjects set out in column 1, that is made on the label of or in an advertisement for a breakfast cereal with milk, shall be accompanied by an indication that it refers to 30 g of the breakfast cereal combined with 125 mL of milk:

(a) "source of protein", set out in item 8;
(b) "excellent source of protein", set out in item 9; and
(c) "more protein", set out in item 10.

***B.01.511.** (1) For greater certainty and subject to subsections (2) to (4), a statement or claim set out in column 4 of the table following section B.01.513 that is made on the label of or in any advertisement for a food may be preceded or followed by other words, numbers, signs or symbols, but none of those shall be interposed between the words, numbers, signs or symbols of the statement or claim.

(2) The words "very", "ultra" and "extra", and all other words, numbers, signs or symbols that modify the nature of a statement or claim, shall not precede or follow the statement or claim.

(3) A statement or claim that is made on the label of or in any advertisement for a food that has not been processed, formulated, reformulated or otherwise modified to meet the conditions set out in column 2 of the table following section B.01.513 shall not be accompanied by the brand name of the food.

(4) Any words, numbers, signs or symbols preceding or following the statement or claim referred to in subsection (3) shall accompany the statement or claim in such a manner that the statement or claim characterizes all foods of that type, and not only the specific food.

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***B.01.512.** If a food meets the conditions set out in column 2 of the table following section B.01.513 for more than one of the subjects set out in column 1, it is not necessary to repeat the common element of the statements or claims set out in column 4 that are used on the label of or in the advertisement for the food, and the remaining elements may be joined by means of a conjunction or punctuation, as appropriate.

Sensory Characteristic

***B.01.513.** (1) No person shall, on the label of or in any advertisement for a food, make the statement or claim "light" or "léger" – including any phonetic rendering of that statement or claim – respecting a sensory characteristic of the food unless the following conditions are met:

(a) if the statement or claim "light" or "léger" is made on the label of a food, the sensory characteristic shall be
  (i) adjacent to, without any intervening printed, written or graphic material,
    (A) the statement or claim, if the statement or claim is made only once, or
    (B) the most prominent statement or claim on the principal display panel or, if none appears there, the most prominent statement or claim elsewhere on the label, if the statement or claim is made more than once, and
  (ii) shown in letters of at least the same size and prominence as
    (A) those of the statement or claim, if the statement or claim is made only once, or
    (B) those of the most prominent statement or claim on the principal display panel or, if none appears there, the most prominent statement or claim elsewhere on the label, if the statement or claim is made more than once;
(b) if the statement or claim "light" or "léger" is made in an advertisement for a food, other than a radio or television advertisement, the sensory characteristic shall be
  (i) adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and
  (ii) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once;
(c) if the statement or claim "light" or "léger" is made in a radio advertisement or in the audio portion of a television advertisement, the sensory characteristic shall immediately precede or follow the statement or claim; and

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

(d) if the statement or claim "light" or "léger" is made in the visual portion of a television advertisement, the sensory characteristic shall

(i) appear concurrently with and for the same amount of time as the statement or claim,

(ii) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and

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(iii) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

(2) Subsection (1) does not apply to

(a) the English statement or claim "light" when used in accordance with subsection 12(1) of the *Maple Products Regulations*; or

(b) the statement or claim "light" or "léger" when used with respect to rum.

TABLE

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
1	Free of energy	The food provides less than 5 Calories or 21 kilojoules per reference amount and serving of stated size.		"energy-free", "free of energy", "no energy", "0 energy", "zero energy", "without energy", "contains no energy", "Calorie-free", "free of Calories", "no Calories", "0 Calories", "zero Calories", "without Calories" or "contains no Calories"
2	Low in energy	The food provides (a) 40 Calories or 167 kilojoules or less per reference amount and serving of stated size and, if the reference amount is 30 g or 30 mL or less, per 50 g; or (b) 120 Calories or 500 kilojoules or less per 100 g, if the food is a prepackaged meal.		"low energy", "low in energy", "low source of energy", "little energy", "low Calorie", "low in Calories", "low source of Calories", "contains only (number) Calories per serving", "contains less than (number) Calories per serving" or "few Calories"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
3	Reduced in energy	(1) The food is processed, formulated, reformulated or otherwise modified so that it provides at least 25% less energy (a) per reference amount of the food, than the reference amount of the similar reference food; or (b) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal. (2) The similar reference food does not meet the conditions set out in column 2 of item 2 for the subject "low in energy" set out in column 1.	The following are identified: (a) the similar reference food; (b) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and (c) the difference in energy value compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in Calories.	"reduced energy", "reduced in energy", "energy-reduced", "less energy", "lower energy", "lower in energy", "reduced Calorie", "reduced in Calories", "Calorie-reduced", "less Calories", "lower Calories", "lower in Calories" or "fewer Calories"
4	Lower in energy	(1) The food provides at least 25% less energy (a) per reference amount of the food, than the reference amount of the reference food of the same food group; or (b) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal. (2) The reference food of the same food group does not meet the conditions set out in column 2 of item 2 for the subject "low in energy" set out in column 1.	The following are identified: (a) the reference food of the same food group; (b) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and (c) the difference in energy value compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in Calories.	"less energy", "lower energy", "lower in energy", "less Calories", "lower Calorie", "lower in Calories" or "fewer Calories"
5	Source of energy	The food provides at least 100 Calories or 420 kilojoules per reference amount and serving of stated size.		"source of energy", "contains energy", "provides energy", "source of Calories", "contains Calories" or "provides Calories"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
6	More energy	The food provides at least 25% more energy, totalling at least 100 more Calories or 420 more kilojoules (a) per reference amount of the food, than the reference amount of the referene food of the same food group or the similar reference food; or (b) per 100 g, than 100 g of the reference food of the same food group or the similar reference food, if the food is a prepackaged meal.	The following are identified: (a) the reference food of the same food group or the similar reference food; (b) the amounts of the food and the reference food of the same food group or the similar reference food being compared, if those amounts are not equal; and (c) the difference in energy value compared to the reference food of the same food group or the similar reference food, per serving of stated size, expressed as a percentage or fraction or in Calories.	"more Calories", "contains more Calories", "higher Calories" or "higher in Calories"
7	Low in protein	The food contains no more than 1 g of protein per 100 g of the food.		"low protein", "low in protein", "low source of protein", "contains only (number) g of protein per serving" or "contains less than (number) g of protein per serving"
8	Source of protein	The food has a protein rating of 20 or more, as determined by official method FO-1, *Determination of Protein Rating*, October 15, 1981, (a) per reasonable daily intake; or (b) per 30 g combined with 125 mL of milk, if the food is a breakfast cereal.		"source of protein", "contains protein", "good source of protein", "high protein", "high in protein" or "provides protein"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
9	Excellent source of protein	The food has a protein rating of 40 or more, as determined by official method FO-1, *Determination of Protein Rating*, October 15, 1981, (a) per reasonable daily intake; or (b) per 30 g combined with 125 mL of milk, if the food is a breakfast cereal.		"excellent source of protein", "very high protein", "very high in protein" or "rich in protein"
10	More protein	The food (a) has a protein rating of 20 or more, as determined by official method FO-1, *Determination of Protein Rating*, October 15, 1981, (i) per reasonable daily intake, or (ii) per 30 g combined with 125 mL of milk, if the food is a breakfast cereal; and (b) contains at least 25% more protein, totalling at least 7 g more, per reasonable daily intake than the reference food of the same food group or the similar reference food.	The following are identified: (a) the reference food of the same food group or the similar reference food; (b) the amounts of the food and the reference food of the same food group or the similar reference food being compared, if those amounts are not equal; and (c) the difference in protein compared to the reference food of the same food group or the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams.	"more protein", "higher protein" or "higher in protein"
11	Free of fat	The food contains (a) less than 0.5 g of fat per reference amount and serving of stated size; or (b) less than 0.5 g of fat per serving of stated size, if the food is a prepackaged meal.		"fat-free", "free of fat", "no fat", "0 fat", "zero fat", "without fat", "contains no fat" or "non-fat"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
12	Low in fat	The food contains (a) 3 g or less of fat per reference amount and serving of stated size and, if the reference amount is 30 g or 30 mL or less, per 50 g; or (b) 3 g or less of fat per 100 g with 30% or less of the energy from fat, if the food is a prepackaged meal.		"low fat", "low in fat", "low source of fat", "little fat", "contains only (number) g of fat per serving" or "contains less than (number) g of fat per serving"
13	Reduced in fat	(1) The food is processed, formulated, reformulated or otherwise modified so that it contains at least 25% less fat (a) per reference amount of the food, than the reference amount of the similar reference food; or (b) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal. (2) The similar reference food does not meet the conditions set out in column 2 of item 12 for the subject "low in fat" set out in column 1.	The following are identified: (a) the similar reference food; (b) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and (c) the difference in fat compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams.	"reduced fat", "reduced in fat", "fat-reduced", "less fat", "lower fat" or "lower in fat"
14	Lower in fat	(1) The food contains at least 25% less fat (a) per reference amount of the food, than the reference amount of the reference food of the same food group; or (b) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal. (2) The reference food of the same food group does not meet the conditions set out in column 2 of item 12 for the subject "low in fat" set out in column 1.	The following are identified: (a) the reference food of the same food group; (b) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and (c) the difference in fat compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in grams.	"less fat", "lower fat" or "lower in fat"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
15	100% fat-free	The food (a) contains less than 0.5 g of fat per 100 g; (b) contains no added fat; and (c) meets the conditions set out in column 2 of item 11 for the subject "free of fat" set out in column 1.		"100% fat-free" or "100% free of fat"
16	(Percentage) fat-free	The food meets the conditions set out in column 2 of item 12 for the subject "low in fat" set out in column 1.	One of the following statements or claims is stated: "low fat" or "low in fat".	"(percentage) fat-free" or (percentage) free of fat"
17	No added fat	(1) The food contains no added fats or oils set out in Division 9, or added butter or ghee, or ingredients that contain added fats or oils, or butter or ghee. (2) The similar reference food contains added fats or oils set out in Division 9, or added butter or ghee.		"no fat added", "no added fat" or "without added fat"
18	Free of saturated fatty acids	The food contains (a) less than 0.2 g saturated fatty acids and less than 0.2 g *trans* fatty acids per reference amount and serving of stated size; or (b) less than 0.2 g saturated fatty acids and less than 0.2 g *trans* fatty acids per serving of stated size, if the food is a prepackaged meal.		"saturated fatty acids-free", "free of saturated fatty acids", "no saturated fatty acids", "0 saturated fatty acids", "zero saturated fatty acids", "without saturated fatty acids", "saturated fat-free", "free of saturated fat", "no saturated fat", "0 saturated fat", "zero saturated fat", "without saturated fat", "saturates-free", "free of saturates", "no saturates", "0 saturates", "zero saturates" or "without saturates"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
19	Low in saturated fatty acids	(1) The food contains 2 g or less of saturated fatty acids and *trans* fatty acids combined (a) per reference amount and serving of stated size; or (b) per 100 g, if the food is a prepackaged meal. (2) The food provides 15% or less energy from the sum of saturated fatty acids and *trans* fatty acids.		"low saturated fatty acids", "low in saturated fatty acids", "low source of saturated fatty acids", "little saturated fatty acids", "contains only (number) g of saturated fatty acids per serving", "contains less than (number) g of saturated fatty acids per serving", "low saturated fat", "low in saturated fat", "low source of saturated fat", "little saturated fat", "contains only (number) g of saturated fat per serving", "contains less than (number) g of saturated fat per serving", "low saturates", "low in saturates", "low source of saturates", "little saturates", "contains only (number) g of saturates per serving" or "contains less than (number) g of saturates per serving"
20	Reduced in saturated fatty acids	(1) The food is processed, formulated, reformulated or otherwise modified, without increasing the content of *trans* fatty acids, so that it contains at least 25% less saturated fatty acids (a) per reference amount of the food, than the reference amount of the similar reference food; or (b) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal. (2) The similar reference food does not meet the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1.	The following are identified: (a) the similar reference food; (b) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and (c) the difference in saturated fatty acids compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams.	"reduced saturated fatty acids", "reduced in saturated fatty acids", "saturated fatty acids-reduced", "less saturated fatty acids", "lower saturated fatty acids", "lower in saturated fatty acids", "fewer saturated fatty acids", "reduced saturated fat", "reduced in saturated fat", "saturated fat-reduced", "less saturated fat", "lower saturated fat", "lower in saturated fat", "reduced saturates", "reduced in saturates", "saturates-reduced", "less saturates", "lower saturates", "lower in saturates" or "fewer saturates"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
21	Lower in saturated fatty acids	(1) The food contains at least 25% less saturated fatty acids and the content of *trans* fatty acids is not higher (a) per reference amount of the food, than the reference amount of the reference food of the same food group; or (b) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal. (2) The reference food of the same food group does not meet the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1.	The following are identified: (a) the reference food of the same food group; (b) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and (c) the difference in saturated fatty acids compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in grams.	"less saturated fatty acids", "lower saturated fatty acids", "lower in saturated fatty acids", "fewer saturated fatty acids", "less saturated fat", "lower saturated fat", "lower in saturated fat", "less saturates", "lower saturates", "lower in saturates" or "fewer saturates"
22	Free of *trans* fatty acids	The food (a) contains less than 0.2 g of *trans* fatty acids (i) per reference amount and serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal; and (b) meets the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1.		"trans fatty acids-free", "free of trans fatty acids", "no trans fatty acids", "0 trans fatty acids", "zero trans fatty acids", "without trans fatty acids", "contains no trans fatty acids", "trans fat-free", "free of trans fat", "no trans fat", "0 trans fat", "zero trans fat", "without trans fat", "contains no trans fat", "trans-free", "free of trans", "no trans", "0 trans", "zero trans" or "without trans"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
23	Reduced in *trans* fatty acids	(1) The food is processed, formulated, reformulated or otherwise modified, without increasing the content of saturated fatty acids, so that it contains at least 25% less *trans* fatty acids (a) per reference amount of the food, than the reference amount of the similar reference food; or (b) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal. (2) The similar reference food does not meet the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1.	The following are identified: (a) the similar reference food; (b) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and (c) the difference in *trans* fatty acids compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams.	"reduced trans", "reduced in trans", "trans-reduced", "reduced trans fatty acids", "reduced in trans fatty acids", "trans fatty acids-reduced", "less trans fatty acids", "lower trans fatty acids", "lower in trans fatty acids", "fewer trans fatty acids", "reduced trans fat", "reduced in trans fat", "trans fat-reduced", "less trans fat", "lower trans fat" or "lower in trans fat"
24	Lower in *trans* fatty acids	(1) The food contains at least 25% less *trans* fatty acids and the content of saturated fatty acids is not higher (a) per reference amount of the food, than the reference amount of the reference food of the same food group; or (b) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal. (2) The reference food of the same food group does not meet the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1.	The following are identified: (a) the reference food of the same food group; (b) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and (c) the difference in *trans* fatty acids compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in grams.	"less trans fatty acids", "lower trans fatty acids", "lower in trans fatty acids", "fewer trans fatty acids", "less trans fat", "lower trans fat", "lower in trans fat", "less trans", "lower trans" or "lower in trans"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
25	Source of omega-3 poly-unsaturated fatty acids	The food contains (a) 0.3 g or more of omega-3 polyunsaturated fatty acids per reference amount and serving of stated size; or (b) 0.3 g or more of omega-3 polyunsaturated fatty acids per 100 g, if the food is a prepackaged meal.		"source of omega-3 polyunsaturated fatty acids", "contains omega-3 polyunsaturated fatty acids", "provides omega-3 polyunsaturated fatty acids", "source of omega-3 polyunsaturated fat", "contains omega-3 polyunsaturated fat", "provides omega-3 polyunsaturated fat", "source of omega-3 polyunsaturates", "contains omega-3 polyunsaturates" or "provides omega-3 polyunsaturates"
26	Source of omega-6 poly-unsaturated fatty acids	The food contains (a) 2 g or more of omega-6 polyunsaturated fatty acids per reference amount and serving of stated size; or (b) 2 g or more of omega-6 polyunsaturated fatty acids per 100 g, if the food is a prepackaged meal.		"source of omega-6 polyunsaturated fatty acids", "contains omega-6 polyunsaturated fatty acids", "provides omega-6 polyunsaturated fatty acids", "source of omega-6 polyunsaturated fat", "contains omega-6 polyunsaturated fat", "provides omega-6 polyunsaturated fat", "source of omega-6 polyunsaturates", "contains omega-6 polyunsaturates" or "provides omega-6 polyunsaturates"
27	Free of cholesterol	The food (a) contains less than 2 mg of cholesterol (i) per reference amount and serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal; and (b) meets the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1.		"cholesterol-free", "free of cholesterol", "no cholesterol", "0 cholesterol", "zero cholesterol", "without cholesterol" or "contains no cholesterol"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
28	Low in cholesterol	The food (a) contains 20 mg or less of cholesterol per (i) reference amount and serving of stated size and, if the reference amount is 30 g or 30 mL or less, per 50 g, or (ii) per 100 g, if the food is a prepackaged meal; and (b) meets the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1.		"low cholesterol", "low in cholesterol", "low source of cholesterol", "little cholesterol", "contains only (number) mg of cholesterol per serving" or "contains less than (number) mg of cholesterol per serving"
29	Reduced in cholesterol	(1) The food is processed, formulated, reformulated or otherwise modified so that it contains at least 25% less cholesterol (a) per reference amount of the food, than the reference amount of the similar reference food; or (b) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal. (2) The similar reference food does not meet the conditions set out in column 2 of item 28 for the subject "low in cholesterol" set out in column 1. (3) The food meets the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1.	The following are identified: (a) the similar reference food; (b) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and (c) the difference in cholesterol compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in milligrams.	"reduced cholesterol", "reduced in cholesterol", "cholesterol-reduced", "less cholesterol", "lower cholesterol" or "lower in cholesterol"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
30	Lower in cholesterol	(1) The food contains at least 25% less cholesterol (a) per reference amount of the food, than the reference amount of the reference food of the same food group; or (b) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal. (2) The reference food of the same food group does not meet the conditions set out in column 2 of item 28 for the subject "low in cholesterol" set out in column 1. (3) The food meets the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1.	The following are identified: (a) the reference food of the same food group; (b) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and (c) the difference in cholesterol compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in milligrams.	"less cholesterol", "lower cholesterol" or "lower in cholesterol"
31	Free of sodium or salt	The food contains (a) less than 5 mg of sodium per reference amount and serving of stated size; or (b) less than 5 mg of sodium per serving of stated size, if the food is a prepackaged meal.		"sodium-free", "free of sodium", "no sodium", "0 sodium", "zero sodium", "without sodium", "contains no sodium", "salt-free", "free of salt", "no salt", "0 salt", "zero salt", "without salt" or "contains no salt"
32	Low in sodium or salt	The food contains (a) 140 mg or less of sodium per reference amount and serving of stated size and, if the reference amount is 30 g or 30 mL or less, per 50 g; or (b) 140 mg or less of sodium per 100 g, if the food is a prepackaged meal.		"low sodium", "low in sodium", "low source of sodium", "little sodium", "contains only (number) mg of sodium per serving", "contains less than (number) mg of sodium per serving", "low salt", "low in salt", "low source of salt", "little salt", "contains only (number) mg of salt per serving" or "contains less than (number) mg salt per serving"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
33	Reduced in sodium or salt	(1) The food is processed, formulated, reformulated or otherwise modified so that it contains at least 25% less sodium (a) per reference amount of the food, than the reference amount of the similar reference food; or (b) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal. (2) The similar reference food does not meet the conditions set out in column 2 of item 32 for the subject "low in sodium or salt" set out in column 1.	The following are identified: (a) the similar reference food; (b) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and (c) the difference in sodium content compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in milligrams.	"reduced sodium"; reduced in sodium", "sodium-reduced", "less sodium", "lower sodium", "lower in sodium", "reduced salt", "reduced in salt", "salt-reduced", "less salt", "lower salt" or "lower in salt"
34	Lower in sodium or salt	(1) The food contains at least 25% less sodium (a) per reference amount of the food, than the reference amount of the reference food of the same food group; or (b) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal. (2) The reference food of the same food group does not meet the conditions set out in column 2 of item 32 for the subject "low in sodium or salt" set out in column 1.	The following are identified: (a) the reference food of the same food group; (b) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and (c) the difference in sodium content compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in milligrams.	"less sodium", "lower sodium", "lower in sodium", "less salt", "lower salt" or "lower in salt"
35	No added sodium or salt	(1) The food contains no added salt, other sodium salts or ingredients that contain sodium that functionally substitute for added salt. (2) The similar reference food does not meet the conditions set out in column 2 of item 32 for the subject "low in sodium or salt" set out in column 1 and contains added salt or other sodium salts.		"unsalted", "without added salt", "no salt added", "no added salt", "without added sodium", "no sodium added" or "no added sodium"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
36	Lightly salted	(1) The food contains at least 50% less added sodium than the sodium added to the similar reference food. (2) The similar reference food does not meet the conditions set out in column 2 of item 32 for the subject "low in sodium or salt" set out in column 1.	The following are identified: (a) the similar reference food; (b) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and (c) the difference in sodium content compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in milligrams.	"lightly salted" or "salted lightly"
37	Free of sugars	The food (a) contains less than 0.5 g of sugars per reference amount and serving of stated size; and (b) with the exception of chewing gum, meets the conditions set out in column 2 of item 1 for the subject "free of energy" set out in column 1.		"sugar-free", "free of sugar", "no sugar", "0 sugar", "zero sugar", "without sugar", "contains no sugar" or "sugarless"
38	Reduced in sugars	The food is processed, formulated, reformulated or otherwise modified so that it contains at least 25% less sugars, totalling at least 5 g less, (a) per reference amount of the food, than the reference amount of the similar reference food; or (b) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal.	The following are identified: (a) the similar reference food; (b) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and (c) the difference in sugars compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams.	"reduced sugar", "reduced in sugar", "sugar-reduced", "less sugar", "lower sugar" or "lower in sugar"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
39	Lower in sugars	The food contains at least 25% less sugars, totalling at least 5 g less, (a) per reference amount of the food, than the reference amount of the reference food of the same food group; or (b) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal.	The following are identified: (a) the reference food of the same food group; (b) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and (c) the difference in sugars compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in grams.	"lower sugar", "lower in sugar" or "less sugar"
40	No added sugars	(1) The food contains no added sugars, no ingredients containing added sugars or ingredients that contain sugars that functionally substitute for added sugars. (2) The sugars content is not increased through some other means except if the functional effect is not to increase the sugars content of the food. (3) The similar reference food contains added sugars.		"no sugar added", "no added sugar" or "without added sugar"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
41	Source of fibre	(1) The food contains 2 g or more (a) of fibre per reference amount and serving of stated size, if no fibre or fibre source is identified in the statement or claim; or (b) of each identified fibre or fibre from an identified fibre source per reference amount and serving of stated size, if a fibre or fibre source is identified in the statement or claim. (2) The food contains at least one ingredient that meets one of the conditions set out in subsection (1), if the food is a prepackaged meal.		"source of fibre", "contains fibre", "provides fibre", "made with fibre", "source of (naming the fibre)", "contains (naming the fibre)", "provides (naming the fibre)", "made with (naming the fibre)", "source of (naming the fibre source)", "contains (naming the fibre source)", "provides (naming the fibre source)", "made with (naming the fibre source)", "source of dietary fibre", "contains dietary fibre", "provides dietary fibre" or "made with dietary fibre"
42	High source of fibre	(1) The food contains 4 g or more (a) of fibre per reference amount and serving of stated size, if no fibre or fibre source is identified in the statement or claim; or (b) of each identified fibre or fibre from an identified fibre source per reference amount and serving of stated size, if a fibre or fibre source is identified in the statement or claim. (2) The food contains at least one ingredient that meets one of the conditions set out in subsection (1), if the food is a prepackaged meal.		"high source of fibre", "high fibre", "high in fibre", "high source of (naming the fibre)", "high (naming the fibre)", "high in (naming the fibre)", "high source of (naming the fibre source)", "high (naming the fibre source)", "high in (naming the fibre source)", "high source of dietary fibre", "high dietary fibre" or "high in dietary fibre"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
43	Very high source of fibre	(1) The food contains 6 g or more (a) of fibre per reference amount and serving of stated size, if no fibre or fibre source is identified in the statement or claim; or (b) of each identified fibre or fibre from an identified fibre source per reference amount and serving of stated size, if a fibre or fibre source is identified in the statement or claim. (2) The food contains at least one ingredient that meets one of the conditions set out in subsection (1), if the food is a prepackaged meal.		"very high source of fibre", "very high fibre", "very high in fibre", "fibre rich", "rich in fibre", "very high source of (naming the fibre)", "very high (naming the fibre)", "very high in (naming the fibre)", "(naming the fibre) rich", "rich in (naming the fibre)", "very high source of (naming the fibre source)", "very high (naming the fibre source)", "very high in (naming the fibre source)", "(naming the fibre source) rich", "rich in (naming the fibre source)", "very high source of dietary fibre", "very high dietary fibre", "very high in dietary fibre", "dietary fibre rich" or "rich in dietary fibre"
44	More fibre	(1) The food contains at least 25% more fibre, totalling at least 1 g more, if no fibre or fibre source is identified in the statement or claim, or at least 25% more of an identified fibre or fibre from an identified fibre source, totalling at least 1 g more, if a fibre or fibre source is identified in the statement or claim (a) per reference amount of the food, than the reference amount of the reference food of the same food group or the similar reference food; or (b) per 100 g, than 100 g of the reference food of the same food group or the similar reference food, if the food is a prepackaged meal. (2) The food contains	The following are identified: (a) the reference food of the same food group or the similar reference food; (b) the amounts of the food and the reference food of the same food group or the similar reference food being compared, if those amounts are not equal; and (c) the difference in fibre compared to the reference food of the same food group or the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams.	"more fibre", "higher fibre", "higher in fibre:, "more (naming the fibre)", "higher (naming the fibre)", "higher in (naming the fibre)", "more (naming the fibre source)", "higher (naming the fibre source)", "higher in (naming the fibre source)", "more dietary fibre", "higher dietary fibre" or "higher in dietary fibre"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
44	(cont'd)	(a) at least 2 g of fibre per reference amount and serving of stated size if no fibre or fibre source is identified in the statement or claim, or at least 2 g of identified fibre or fibre from an identified fibre source per reference amount and serving of stated size if a fibre or fibre source is identified in the statement or claim; or (b) at least one ingredient that meets the conditions set out in column 2 of item 41 for the subject "source of fibre" set out in column 1, if the food is a prepackaged meal.		
45	Light in energy or fat	The food meets the conditions set out in column 2 (a) of item 3 for the subject "reduced in energy" set out in column 1; or (b) of item 13 for the subject "reduced in fat" set out in column 1.	The following are identified: (a) the similar reference food; (b) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and (c) the difference in energy or fat value compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in Calories or grams.	"light" or "lite"
46	Lean	The food (a) is meat or poultry that has not been ground, a marine or fresh water animal or a product of any of these; and (b) contains 10% or less fat.		"lean"

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Subject	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement	Column 4 Statement or Claim
47	Extra lean	The food (a) is meat or poultry that has not been ground, a marine or fresh water animal or a product of any of these; and (b) contains 7.5% or less fat.		"extra lean"

12-12-02

[**B.01.514** to **B.01.599** reserved]

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Health Claims

Languages

***B.01.600.** A statement or claim set out in column 1 of the table following section B.01.603 that appears on the label of a food shall be

(a) in English and French; or
(b) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

Statements or Claims

***B.01.601.** (1) A food with a label or advertisement that carries a statement or claim set out in column 1 of the table following section B.01.603 is exempt from the provisions of the Act and its Regulations with respect to drugs, and from subsections 3(1) and (2) of the Act, if

(a) the food meets the applicable conditions set out in column 2;
(b) the label of or the advertisement for the food meets the applicable conditions set out in column 3; and
(c) the food is not
  (i) intended solely for children under two years of age, or
  (ii) a food represented for use in a very low energy diet.

(2) Subsection (1) does not apply to a food that comes within the definition of "drug" as defined in section 2 of the Act for a reason other than the fact that its label or advertisement carries a statement or claim referred to in that subsection.

(3) Subsection (1) applies even if the word "graisses" in the French version of the statement or claim is replaced by the word "lipides".

12-12-02

***B.01.602.** (1) The information required under the conditions set out in column 3 of the table following section B.01.603 that appears in an advertisement for a food that is not a prepackaged product, or in an advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, shall,

(a) in the case of an advertisement, other than a radio or television advertisement, be
  (i) adjacent to, without any intervening printed, written or graphic material, the statement or claim set out in column 1, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and
  (ii) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once;

(b) in the case of a radio advertisement or the audio portion of a television advertisement, immediately precede or follow the statement or claim set out in column 1; or

(c) in the case of a television advertisement, be communicated
  (i) in the audio mode, if the statement or claim set out in column 1 is made only in the audio portion of the advertisement or in both the audio and visual portions, or
  (ii) in the audio or visual mode, if the statement or claim set out in column 1 is made only in the visual portion of the advertisement.

(2) The information that is communicated in the visual mode of a television advertisement in accordance with subparagraph (1)(c)(ii) shall
(a) appear concurrently with and for at least the same amount of time as the statement or claim;
(b) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and
(c) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

*B.01.603. For greater certainty, a statement or claim set out in column 1 of the table following this section that is made on the label of or in any advertisement for a food may be preceded or followed by other words, numbers, signs or symbols, but none of those shall be interposed between the words, numbers, signs or symbols of the statement or claim.

12-12-02

TABLE

Item	Column 1 Statement or Claim	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement
1	(1) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is sodium-free." (2) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is low in sodium." (3) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is a good source of potassium and is sodium-free." (4) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is a good source of potassium and is low in sodium." (5) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is high in potassium and is sodium-free."	The food (a) other than a vegetable or fruit, does not meet the conditions set out in column 2 of item 2 of the table following section B.01.513 for the subject "low in energy" set out in column 1; (b) contains at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient (i) per reference amount and per serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal; (c) meets the conditions set out in column 2 of item 19 of the table following section B.01.513 for the subject "low in saturated fatty acids" set out in column 1; (d) contains 0.5% or less alcohol; (e) meets the conditions set out in column 2 of item 31 of the table following section B.01.513 for the subject "free of sodium or salt" set out in column 1, if the label of or advertisement for the food carries statement or claim (1), (3) or (5) set out in column 1 of this item; (f) meets the conditions set out in column 2 of item 32 of the table following section B.01.513 for the subject "low in sodium or salt" set out in column 1, if the label of or advertisement for the food carries statement or claim (2), (4) or (6) set out in column 1 of this item; and	(1) If the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the nutrition facts table shall include the amount of potassium, in accordance with subsection B.01.402(2). (2) If the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of sodium and potassium per serving of stated size, in accordance with section B.01.602 if applicable.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Statement or Claim	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement
1. (cont'd)	(6) "A healty diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is high in potassium and is low in sodium."	(g) contains 350 mg or more of potassium, if the label of or advertisement for the food carries statement or claim (3), (4), (5) or (6) set out in column 1 of this item, (i) per reference amount and per serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal.	
2	(1) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and reduce the risk of osteoporosis. (Naming the food) is a good source of calcium." (2) "A healty diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is high in calcium." (3) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naing the food) is an excellent source of calcium." (4) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is very high in calcium."	The food (a) other than a vegetable or fruit, does not meet the conditions set out in column 2 of item 2 of the table following section B.01.513 for the subject "low in energy" set out in column 1; (b) contains no more phosphorus, excluding that provided by phytate, than calcium; (c) contains 0.5% or less alcohol; (d) contains, if the label of or advertisement for the food carries statement or claim (1) or (2) set out in column 1 of this item, (i) 200 mg or more of calcium per reference amount and per serving of stated size, or (ii) 300 mg or more of calcium per serving of stated size, if the food is a prepackaged meal; (e) contains, if the label of or advertisement for the food carries statement or claim (3), (4), (5) or (6) set out in column 1 of this item,	(1) If the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the nutrition facts table shall include the amount of vitamin D and phosphorus, in accordance with subsection B.01.402(2). (2) If the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of vitamin D, calcium and phosphorus per serving of stated size, in accordance with section B.01.602 if applicable.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Statement or Claim	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement
2. (cont'd)	(5) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is an excellent source of calcium and vitamin D."	(i) 275 mg or more of calcium per reference amount and per serving of stated size, or (ii) 400 mg or more of calcium per serving of stated size, if the food is a prepackaged meal; and	
	(6) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is very high in calcium and vitamin D."	(f) contains 1.25 µg or more of vitamin D, if the label of or advertisement for the food carries statement or claim (5) or (6) set out in column 1 of this item, (i) per reference amount and per serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal.	
3	(1) "A healthy diet low in saturated and trans fats may reduce the risk of heart disease. (Naming the food) is free of saturated and trans fats." (2) "A healthy diet low in saturated and trans fats may reduce the risk of heart disease. (Naming the food) is low in saturated and trans fats."	The food (a) other than a vegetable or fruit, does not meet the conditions set out in column 2 of item 2 of the table following section B.01.513 for the subject "low in energy" set out in column 1; (b) contains at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient (i) per reference amount and per serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal; (c) contains 100 mg or less of cholesterol per 100 g of food; (d) contains 0.5% or less alcohol;	If the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of saturated fatty acids and *trans* fatty acids per serving of stated size; in accordance with section B.01.602 if applicable.

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Statement or Claim	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement
3. (cont'd)		(e) if it is a fat or an oil, meets the conditions set out in (i) column 2 of item 25 of the table following section B.01.513 for the subject "source of omega-3 polyunsaturated fatty acids" set out in column 1, (ii) column 2 of item 26 of the table following section B.01.513 for the subject "source of omega-6 polyunsaturated fatty acids" set out in column 1, or (iii) subparagraphs (i) and (ii); (f) contains (i) 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less, or (ii) 960 mg or less of sodium per serving of stated size, if the food is a prepackaged meal; (g) meets the conditions set out in column 2 of item 18 of the table following section B.01.513 for the subject "free of saturated fatty acids" set out in column 1, if the label of or advertisement for the food carries statement or claim (1) set out in column 1 of this item; and (h) meets the conditions set out in column 2 of item 19 of the table following section B.01.513 for the subject "low in saturated fatty acids" set out in column 1, if the label of or advertisement for the food carries statement or claim (2) set out in column 1 of this item.	

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Statement or Claim	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement
4	"A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer."	The food (a) is one of the following vegetables, fruit, or juice, and may contain only sweetening agents, food additives as permitted by these Regulations, salt, herbs, spices, seasonings or water: (i) a fresh, frozen, canned or dried vegetable, (ii) a fresh, frozen, canned or dried fruit, (iii) a vegetable or fruit juice, or (iv) a combination of the foods set out in subparagraphs (i) to (iii); (b) is not one of the following: (i) potatoes, yams, cassava, plantain, corn, mushrooms, mature legumes and their juices, (ii) vegetables or fruit used as condiments, garnishes or flavourings, including maraschino cherries, glacé fruit, candied fruit and onion flakes, (iii) jams or jam-type spreads, marmalades, preserves and jellies, (iv) olives, or (v) powdered vegetables or fruit; and (c) contains 0.5% or less alcohol.	

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

Item	Column 1 Statement or Claim	Column 2 Conditions – Food	Column 3 Conditions – Label or Advertisement
5	(1) "Won't cause cavities." (2) "Does not promote tooth decay." (3) "Does not promote dental caries." (4) "Non-cariogenic."	The food is a chewing gum, hard candy or breath-freshening product that (a) contains 0.25% or less starch, dextrins, mono-, di- and oligosaccharides or other fermentable carbohydrates combined; or (b) does not, if it contains more than 0.25% fermentable carbohydrates, lower plaque pH below 5.7 by bacterial fermentation during 30 minutes after consumption as measured by the indwelling plaque pH test, referred to in "Identification of Low Caries Risk Dietary Components" by T.N. Imfeld, Volume 11, Monographs in Oral Science, 1983.	If the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the nutrition facts table shall include the amount of sugar alcohols, if present, in accordance with subsection B.01.402(2).

*** Coming into force identical for all sections from B.01.400 to B.01.603.**

***Schedule L**

(Sections B.01.402, B.01.403, B.01.450 and B.01.454 to B.01.465)

NUTRITION FACTS TABLE FORMATS

*** SCHEDULE L COMES INTO FORCE** *on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

Disclaimer:

The figures for NUTRITION FACTS TABLE FORMATS in Schedule L illustrate the requirements specified in the Regulations. If these figures are downloaded from the PDF files, they may be inaccurate. Individuals interested in obtaining an electronic version of these figures are invited to address their request:

by e-mail at http://www.hc-sc.gc.ca/hpfb-dgpsa/onpp-bppn/labelling-etiquetage/index_e.html

by phone at 613-941-9252

*(R) Minor correction

60-71, October 29, 2003 (R)
Replaces page 60-71, December 12, 2002

Standard Format

Figure 1.1(E)

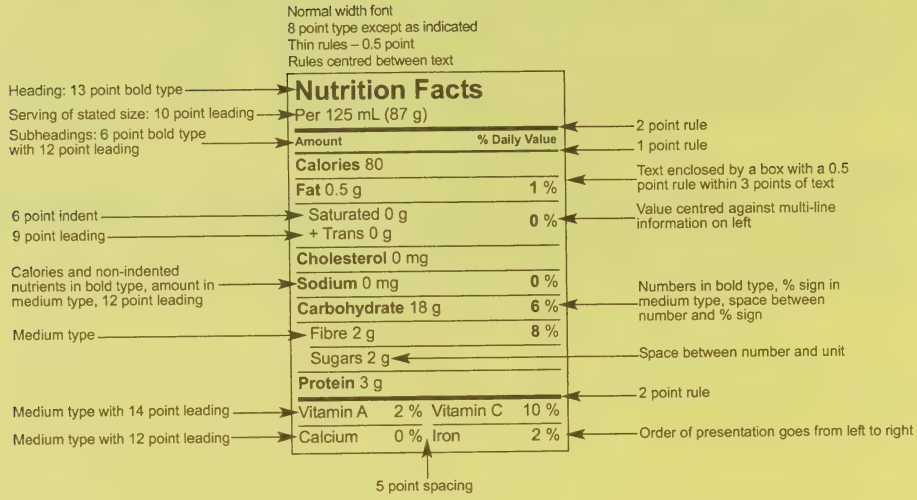


Figure 1.1(F)

Valeur nutritive
par 125 mL (87 g)

Teneur	% valeur quotidienne
Calories 80	
Lipides 0,5 g	1 %
saturés 0 g + trans 0 g	0 %
Cholestérol 0 mg	
Sodium 0 mg	0 %
Glucides 18 g	6 %
Fibres 2 g	8 %
Sucres 2 g	
Protéines 3 g	

Vitamine A	2 %	Vitamine C	10 %
Calcium	0 %	Fer	2 %

Note: Same format specifications as in Figure 1.1(E).

Figures 1.2(E) and (F)

Follow Figures 1.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 1.3(E) and (F)

Follow Figures 1.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 1.4(E) and (F)

Follow Figures 1.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings, by 2 points where there is a rule and by 1 point where there is no rule; thin rules are reduced to 0.25 point.

Figures 1.5(E) and (F)

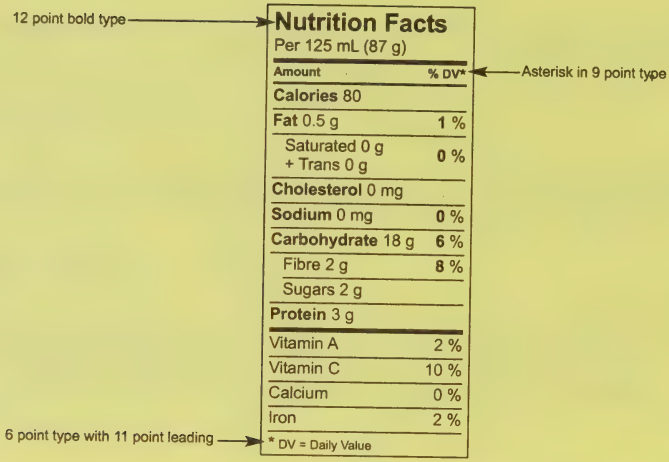
Follow Figures 1.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type.

Figures 1.6(E) and (F)

Follow Figures 1.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings, by 3 points where there is a rule and by 2 points where there is no rule; thin rules are reduced to 0.25 point.

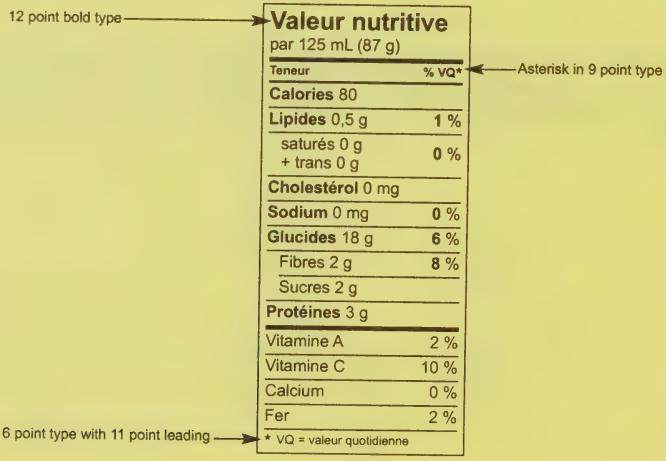
Narrow Standard Format

Figure 2.1(E)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 2.1(F)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figures 2.2(E) and (F)

Follow Figures 2.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point; the heading is displayed in 11 point bold type.

Figures 2.3(E) and (F)

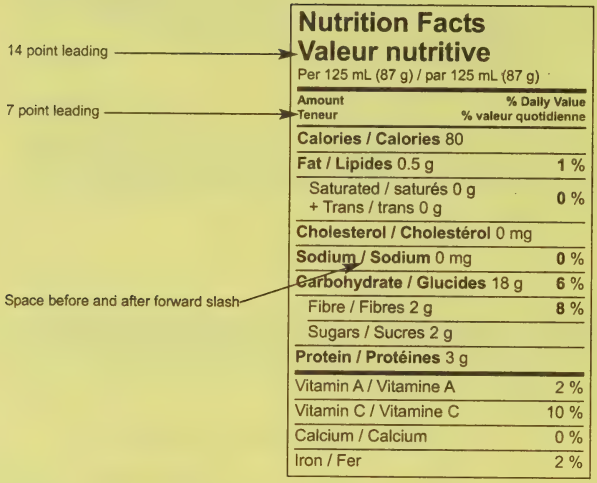
Follow Figures 2.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point; the heading is displayed in 10 point bold type.

Figures 2.4(E) and (F)

Follow Figures 2.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type.

Bilingual Standard Format

Figure 3.1(B)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.
French terms may appear first.

Figure 3.2(B)

Follow Figure 3.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

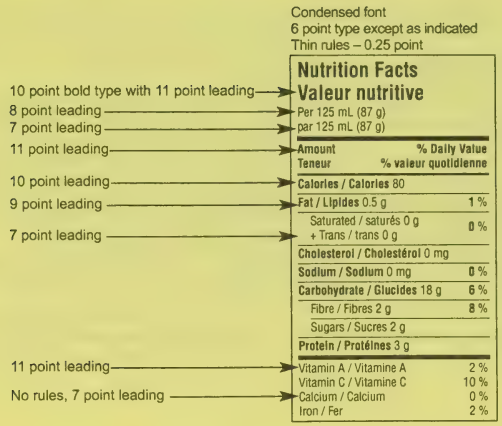
Figure 3.3(B)

Follow Figure 3.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 3.4(B)

Follow Figure 3.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type with leading reduced by 3 points.

Figure 3.5(B)



Note: Same format specifications as in Figure 3.1(B) except as otherwise indicated.
French terms may appear first.

Figure 3.6(B)

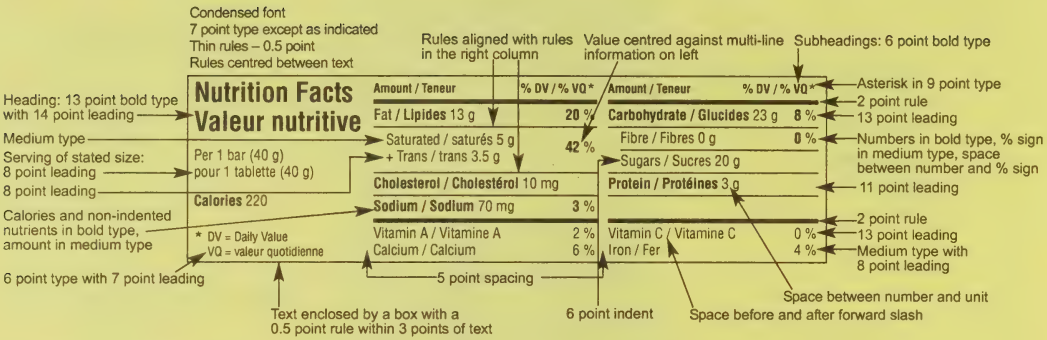
Follow Figure 3.5(B) except: leading is reduced by 1 point where there is a rule.

Figure 3.7(B)

Follow Figure 3.5(B) except: the heading may be displayed in 9 point bold type with leading reduced by 3 points; leading may be reduced by 2 points where there is a rule, and by 1 point where there is no rule except for subheadings; box enclosing text may be displayed with a 0.25 point rule within 1 point of text; 2 point rules may be reduced to 1.5 points and the 1 point rule may be reduced to 0.75 point.

Bilingual Horizontal Format

Figure 4.1(B)

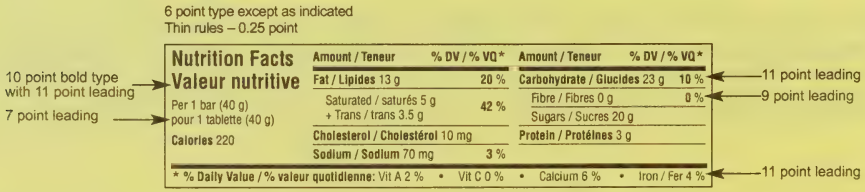


Note: French terms may appear first.

Figure 4.2(B)

Follow Figure 4.1(B) except: serving of stated size, Calories and nutrients are displayed in 6 point type; the heading is displayed in 10 point bold type with leading reduced by 3 points; the leading is reduced by 1 point in the right column and the information in the other columns is adjusted accordingly.

Figure 4.3(B)



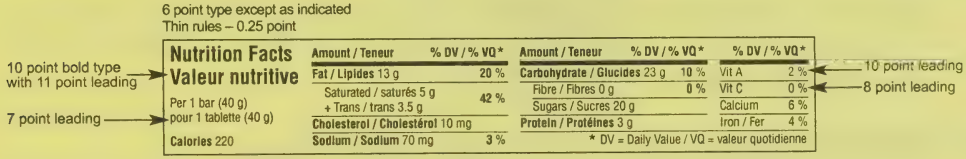
Note: Same format specifications as in Figure 4.1(B) except as otherwise indicated.
French terms may appear first.

Bilingual Horizontal Format (*continued*)

Figure 4.4(B)

Follow Figure 4.3(B) except: the leading is reduced by 1 point in the right column and the information in the other columns is adjusted accordingly.

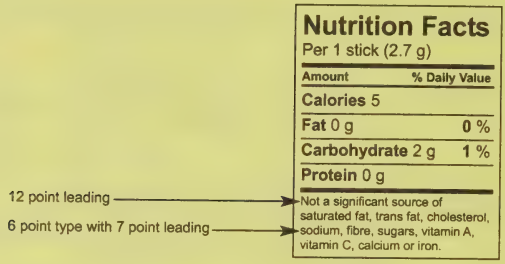
Figure 4.5(B)



Note: Same format specifications as in Figure 4.1(B) except as otherwise indicated.
French terms may appear first.

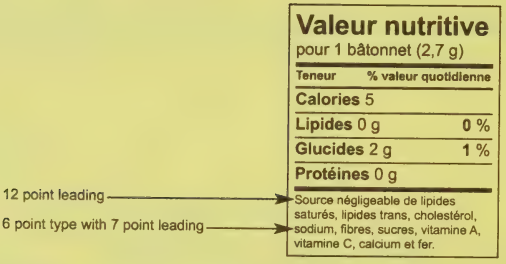
Simplified Standard Format

Figure 5.1(E)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 5.1(F)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Simplified Standard Format (*continued*)

Figures 5.2(E) and (F)

Follow Figures 5.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 5.3(E) and (F)

Follow Figures 5.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 5.4(E) and (F)

Follow Figures 5.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings, by 2 points where there is a rule, and by 1 point where there is no rule, except for the footnote; thin rules are reduced to 0.25 point.

Figures 5.5(E) and (F)

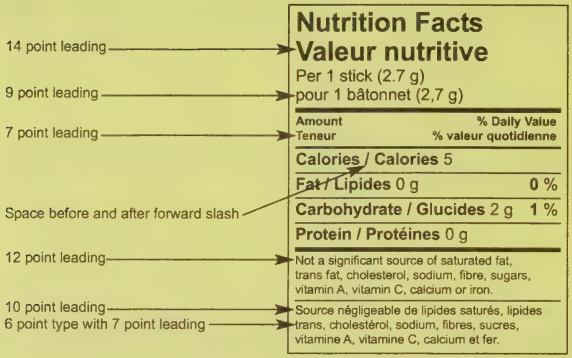
Follow Figures 5.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type.

Figures 5.6(E) and (F)

Follow Figures 5.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings, by 3 points where there is a rule, and by 2 points where there is no rule, except for the footnote; thin rules are reduced to 0.25 point.

Bilingual Simplified Standard Format

Figure 6.1(B)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.
French terms may appear first.

Figure 6.2(B)

Follow Figure 6.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 6.3(B)

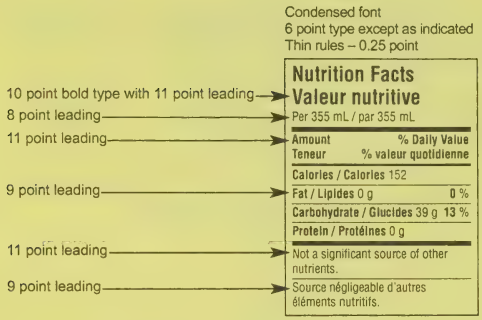
Follow Figure 6.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 6.4(B)

Follow Figure 6.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type with leading reduced by 3 points.

Bilingual Simplified Standard Format (*continued*)

Figure 6.5(B)



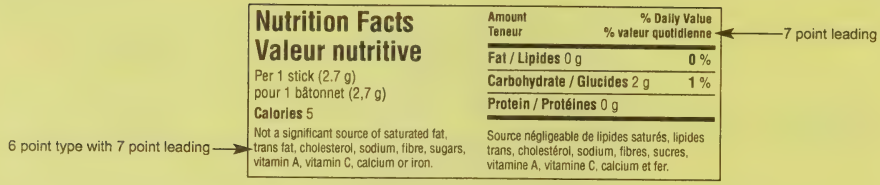
Note: Same format specifications as in Figure 6.1(B) except as otherwise indicated.
French terms may appear first.

Figure 6.6(B)

Follow Figure 6.5(B) except: leading is reduced by 1 point where there is a rule.

Bilingual Simplified Horizontal Format

Figure 7.1(B)

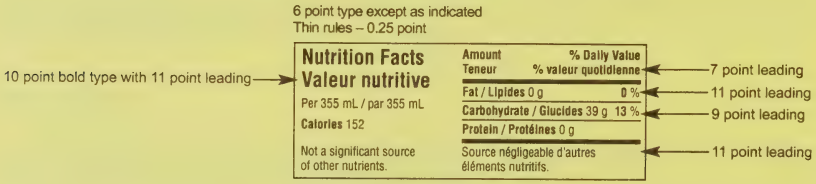


Note: Same format specifications as in Figure 4.1(B) except as otherwise indicated.
French terms may appear first.

Figure 7.2(B)

Follow Figure 7.1(B) except: serving of stated size, Calories and nutrients are displayed in 6 point type; the heading is displayed in 10 point bold type with leading reduced by 3 points; the leading is reduced by 1 point where there is a rule and the information in the other column is adjusted accordingly.

Figure 7.3(B)



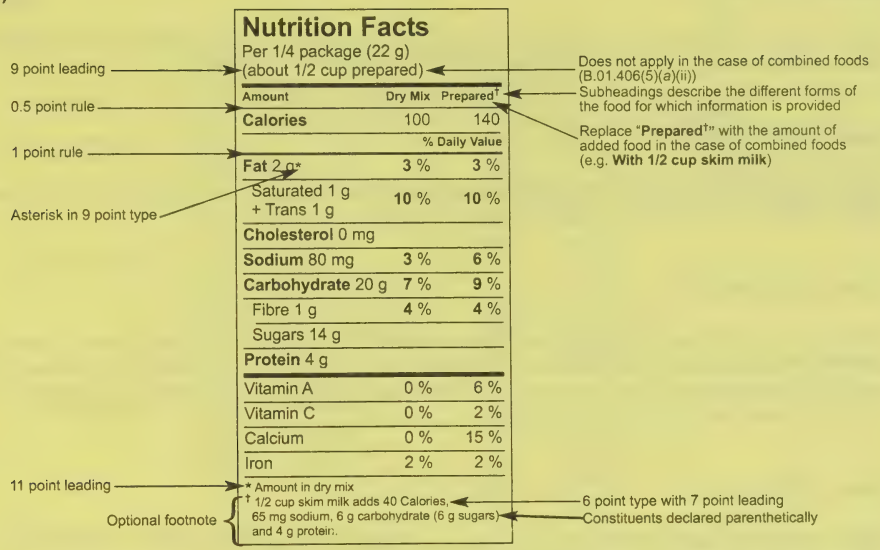
Note: Same format specifications as in Figure 7.1(B) except as otherwise indicated.
French terms may appear first.

Figure 7.4(B)

Follow Figure 7.3(B) except: leading is reduced by 1 point where there is a rule and the information in the other column is adjusted accordingly.

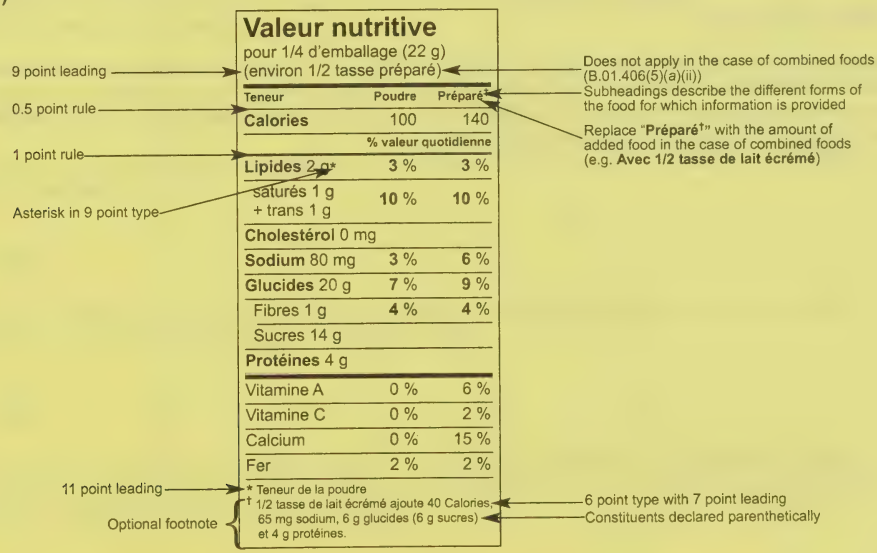
Dual Format – Foods Requiring Preparation

Figure 8.1(E)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 8.1(F)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Dual Format – Foods Requiring Preparation (*continued*)

Figures 8.2(E) and (F)

Follow Figures 8.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 8.3(E) and (F)

Follow Figures 8.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 8.4(E) and (F)

Follow Figures 8.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings and the footnotes, by 2 points where there is a rule, and by 1 point where there is no rule; thin rules are reduced to 0.25 point.

Figures 8.5(E) and (F)

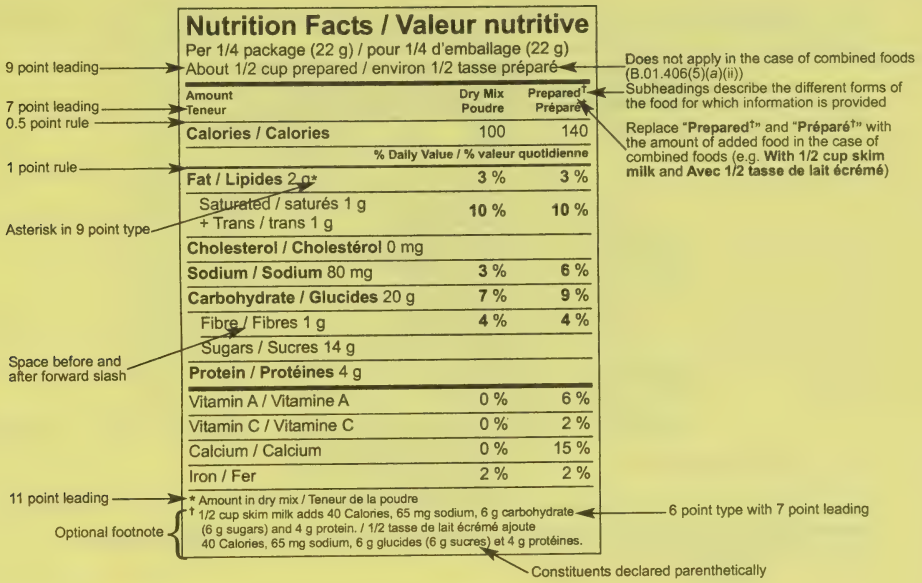
Follow Figures 8.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type; leading for the footnote is reduced by 1 point.

Figures 8.6(E) and (F)

Follow Figures 8.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings, by 3 points where there is a rule, and by 2 points where there is no rule and for the footnotes; thin rules are reduced to 0.25 point.

Bilingual Dual Format – Foods Requiring Preparation

Figure 9.1(B)



Nutrition Facts / Valeur nutritive

Per 1/4 package (22 g) / pour 1/4 d'emballage (22 g)

About 1/2 cup prepared / environ 1/2 tasse préparé

Amount / Teneur	Dry Mix / Poudre	Prepared† / Préparé†
Calories / Calories	100	140
	% Daily Value / % valeur quotidienne	
Fat / Lipides 2 g*	3 %	3 %
Saturated / saturés 1 g + Trans / trans 1 g	10 %	10 %
Cholesterol / Cholestérol 0 mg		
Sodium / Sodium 80 mg	3 %	6 %
Carbohydrate / Glucides 20 g	7 %	9 %
Fibre / Fibres 1 g	4 %	4 %
Sugars / Sucres 14 g		
Protein / Protéines 4 g		
Vitamin A / Vitamine A	0 %	6 %
Vitamin C / Vitamine C	0 %	2 %
Calcium / Calcium	0 %	15 %
Iron / Fer	2 %	2 %

* Amount in dry mix / Teneur de la poudre

† 1/2 cup skim milk adds 40 Calories, 65 mg sodium, 6 g carbohydrate (6 g sugars) and 4 g protein. / 1/2 tasse de lait écrémé ajoute 40 Calories, 65 mg sodium, 6 g glucides (6 g sucres) et 4 g protéines.

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.
French terms may appear first.

Figure 9.2(B)

Follow Figure 9.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 9.3(B)

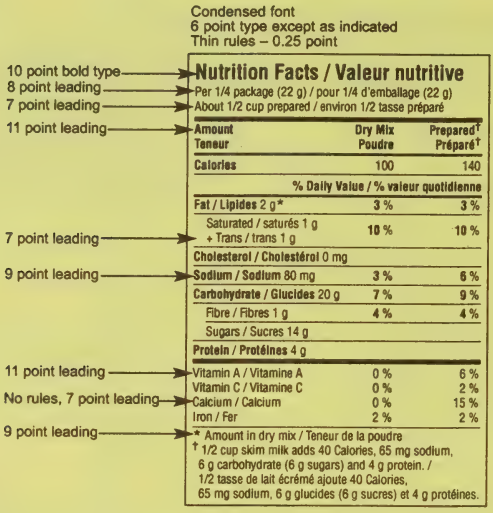
Follow Figure 9.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 9.4(B)

Follow Figure 9.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type; leading for the footnote is reduced by 1 point.

Bilingual Dual Format – Foods Requiring Preparation (*continued*)

Figure 9.5(B)



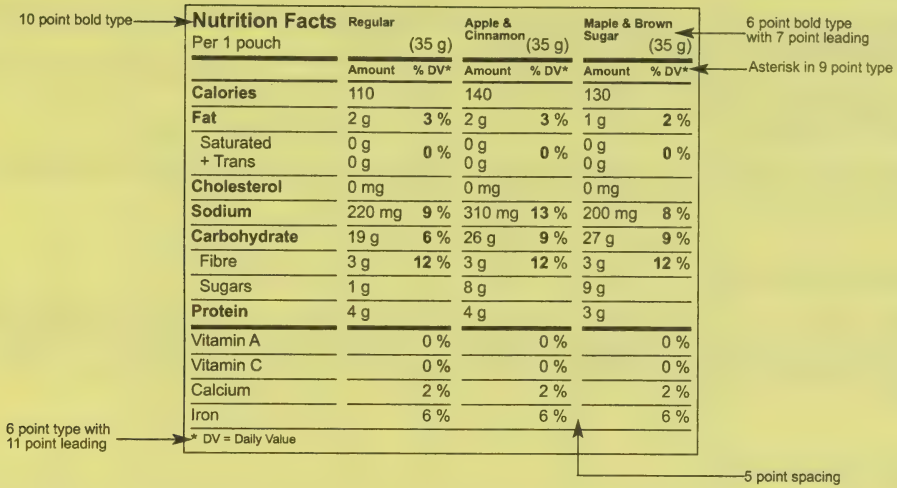
Note: Same format specifications as in Figure 9.1(B) except as otherwise indicated. French terms may appear first.

Figure 9.6(B)

Follow Figure 9.5(B) except: leading is reduced by 1 point where there is a rule.

Aggregate Format – Different Kinds of Foods

Figure 10.1(E)

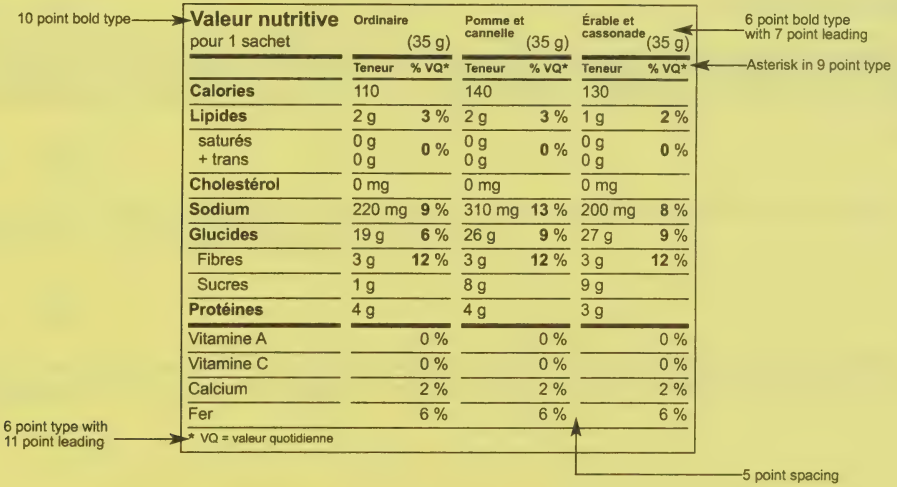


Nutrition Facts Per 1 pouch	Regular (35 g)		Apple & Cinnamon (35 g)		Maple & Brown Sugar (35 g)	
	Amount	% DV*	Amount	% DV*	Amount	% DV*
Calories	110		140		130	
Fat	2 g	**3 %**	2 g	**3 %**	1 g	**2 %**
Saturated + Trans	0 g 0 g	**0 %**	0 g 0 g	**0 %**	0 g 0 g	**0 %**
Cholesterol	0 mg		0 mg		0 mg	
Sodium	220 mg	**9 %**	310 mg	**13 %**	200 mg	**8 %**
Carbohydrate	19 g	**6 %**	26 g	**9 %**	27 g	**9 %**
Fibre	3 g	**12 %**	3 g	**12 %**	3 g	**12 %**
Sugars	1 g		8 g		9 g	
Protein	4 g		4 g		3 g	
Vitamin A		0 %		0 %		0 %
Vitamin C		0 %		0 %		0 %
Calcium		2 %		2 %		2 %
Iron		6 %		6 %		6 %

* DV = Daily Value

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 10.1(F)



Valeur nutritive pour 1 sachet	Ordinaire (35 g)		Pomme et cannelle (35 g)		Érable et cassonade (35 g)	
	Teneur	% VQ*	Teneur	% VQ*	Teneur	% VQ*
Calories	110		140		130	
Lipides	2 g	**3 %**	2 g	**3 %**	1 g	**2 %**
saturés + trans	0 g 0 g	**0 %**	0 g 0 g	**0 %**	0 g 0 g	**0 %**
Cholestérol	0 mg		0 mg		0 mg	
Sodium	220 mg	**9 %**	310 mg	**13 %**	200 mg	**8 %**
Glucides	19 g	**6 %**	26 g	**9 %**	27 g	**9 %**
Fibres	3 g	**12 %**	3 g	**12 %**	3 g	**12 %**
Sucres	1 g		8 g		9 g	
Protéines	4 g		4 g		3 g	
Vitamine A		0 %		0 %		0 %
Vitamine C		0 %		0 %		0 %
Calcium		2 %		2 %		2 %
Fer		6 %		6 %		6 %

* VQ = valeur quotidienne

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Aggregate Format – Different Kinds of Foods (*continued*)

Figures 10.2(E) and (F)

Follow Figures 10.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 10.3(E) and (F)

Follow Figures 10.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 10.4(E) and (F)

Follow Figures 10.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type; leading is reduced by 1 point for subheadings and the footnote, by 2 points where there is a rule, and by 1 point where there is no rule; thin rules are reduced to 0.25 point.

Figures 10.5(E) and (F)

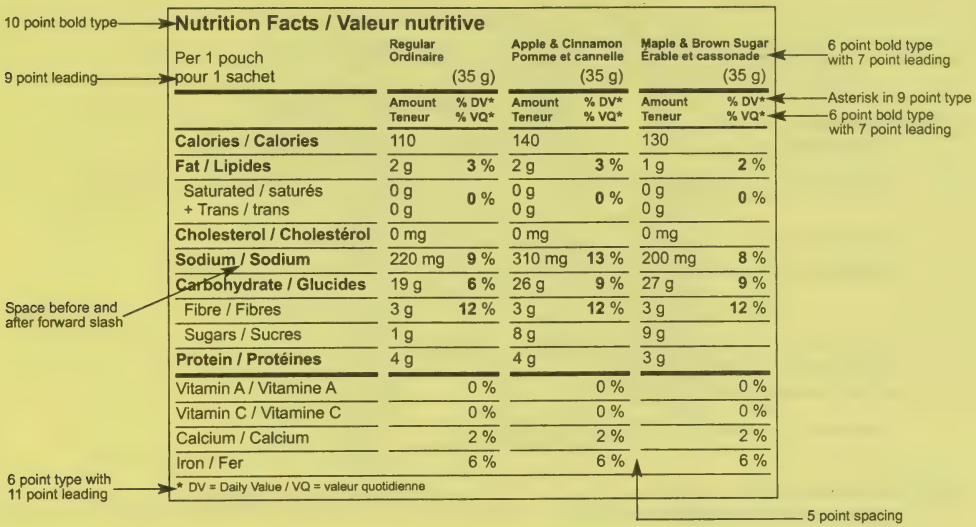
Follow Figures 10.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; leading for the footnote is reduced by 1 point.

Figures 10.6(E) and (F)

Follow Figures 10.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type; leading is reduced by 1 point for subheadings, by 3 points where there is a rule, and by 2 points where there is no rule and for the footnote; thin rules are reduced to 0.25 point.

Bilingual Aggregate Format – Different Kinds of Foods

Figure 11.1(B)



Nutrition Facts / Valeur nutritive

Per 1 pouch / pour 1 sachet	Regular / Ordinaire (35 g)		Apple & Cinnamon / Pomme et cannelle (35 g)		Maple & Brown Sugar / Érable et cassonade (35 g)	
	Amount / Teneur	% DV* / % VQ*	Amount / Teneur	% DV* / % VQ*	Amount / Teneur	% DV* / % VQ*
Calories / Calories	110		140		130	
Fat / Lipides	2 g	**3** %	2 g	**3** %	1 g	**2** %
Saturated / saturés + Trans / trans	0 g 0 g	**0** %	0 g 0 g	**0** %	0 g 0 g	**0** %
Cholesterol / Cholestérol	0 mg		0 mg		0 mg	
Sodium / Sodium	220 mg	**9** %	310 mg	**13** %	200 mg	**8** %
Carbohydrate / Glucides	19 g	**6** %	26 g	**9** %	27 g	**9** %
Fibre / Fibres	3 g	**12** %	3 g	**12** %	3 g	**12** %
Sugars / Sucres	1 g		8 g		9 g	
Protein / Protéines	4 g		4 g		3 g	
Vitamin A / Vitamine A		0 %		0 %		0 %
Vitamin C / Vitamine C		0 %		0 %		0 %
Calcium / Calcium		2 %		2 %		2 %
Iron / Fer		6 %		6 %		6 %

* DV = Daily Value / VQ = valeur quotidienne

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.
French terms may appear first.

Figure 11.2(B)

Follow Figure 11.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 11.3(B)

Follow Figure 11.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 11.4(B)

Follow Figure 11.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; leading for the footnote is reduced by 1 point.

Bilingual Aggregate Format – Different Kinds of Foods (*continued*)

Figure 11.5(B)

Condensed font
6 point type except as indicated
Thin rules – 0.25 point

7 point leading
11 point leading
10 point leading
7 point leading
9 point leading
11 point leading
No rules, 7 point leading
9 point leading

Nutrition Facts / Valeur nutritive

Per 1 pouch / pour 1 sachet	Regular / Ordinaire (35 g)		Apple & Cinnamon / Pomme et cannelle (35 g)		Maple & Brown Sugar / Érable et cassonade (35 g)	
	Amount / Teneur	% DV* / % VQ*	Amount / Teneur	% DV* / % VQ*	Amount / Teneur	% DV* / % VQ*
Calories / Calories	110		140		130	
Fat / Lipides	2 g	3 %	2 g	3 %	1 g	2 %
Saturated / saturés + Trans / trans	0 g + 0 g	0 %	0 g + 0 g	0 %	0 g + 0 g	0 %
Cholesterol / Cholestérol	0 mg		0 mg		0 mg	
Sodium / Sodium	220 mg	9 %	310 mg	13 %	200 mg	8 %
Carbohydrate / Glucides	19 g	6 %	26 g	9 %	27 g	9 %
Fibre / Fibres	3 g	12 %	3 g	12 %	3 g	12 %
Sugars / Sucres	1 g		8 g		9 g	
Protein / Protéines	4 g		4 g		3 g	
Vitamin A / Vitamine A		0 %		0 %		0 %
Vitamin C / Vitamine C		0 %		0 %		0 %
Calcium / Calcium		2 %		2 %		2 %
Iron / Fer		6 %		6 %		6 %

* DV = Daily Value / VQ = valeur quotidienne

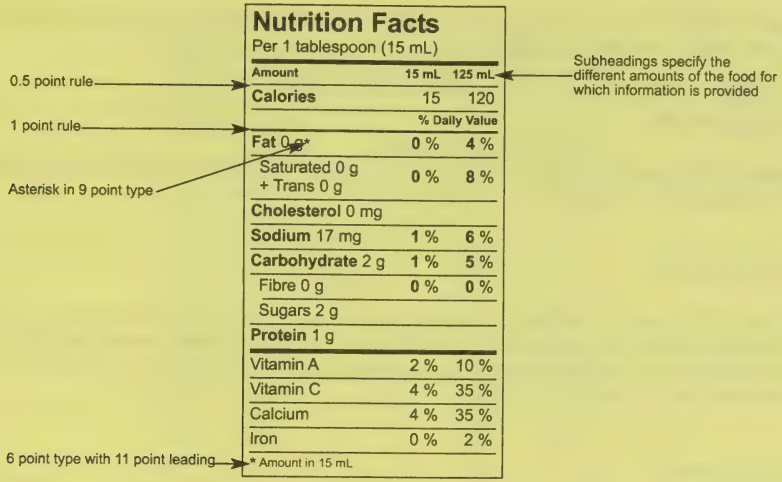
Note: Same format specifications as in Figure 11.1(B) except as otherwise indicated.
French terms may appear first.

Figure 11.6(B)

Follow Figure 11.5(B) except: leading is reduced by 1 point where there is a rule.

Dual Format – Different Amounts of Food

Figure 12.1(E)



Nutrition Facts

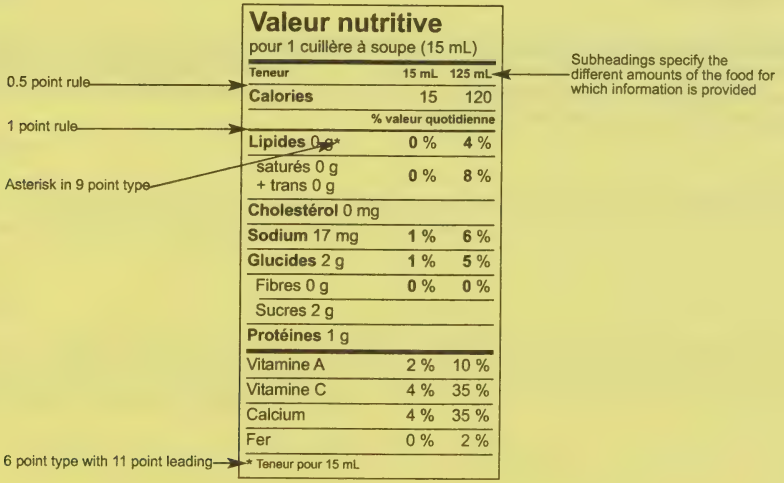
Per 1 tablespoon (15 mL)

Amount	15 mL	125 mL
Calories	15	120
	% Daily Value	
Fat 0 g*	**0** %	**4** %
Saturated 0 g + Trans 0 g	**0** %	**8** %
Cholesterol 0 mg		
Sodium 17 mg	**1** %	**6** %
Carbohydrate 2 g	**1** %	**5** %
Fibre 0 g	**0** %	**0** %
Sugars 2 g		
Protein 1 g		
Vitamin A	2 %	10 %
Vitamin C	4 %	35 %
Calcium	4 %	35 %
Iron	0 %	2 %

* Amount in 15 mL

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 12.1(F)



Valeur nutritive

pour 1 cuillère à soupe (15 mL)

Teneur	15 mL	125 mL
Calories	15	120
	% valeur quotidienne	
Lipides 0 g*	**0** %	**4** %
saturés 0 g + trans 0 g	**0** %	**8** %
Cholestérol 0 mg		
Sodium 17 mg	**1** %	**6** %
Glucides 2 g	**1** %	**5** %
Fibres 0 g	**0** %	**0** %
Sucres 2 g		
Protéines 1 g		
Vitamine A	2 %	10 %
Vitamine C	4 %	35 %
Calcium	4 %	35 %
Fer	0 %	2 %

* Teneur pour 15 mL

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Dual Format – Different Amounts of Food (*continued*)

Figures 12.2(E) and (F)

Follow Figures 12.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 12.3(E) and (F)

Follow Figures 12.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 12.4(E) and (F)

Follow Figures 12.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings and the footnote, by 2 points where there is a rule, and by 1 point where there is no rule; thin rules are reduced to 0.25 point.

Figures 12.5(E) and (F)

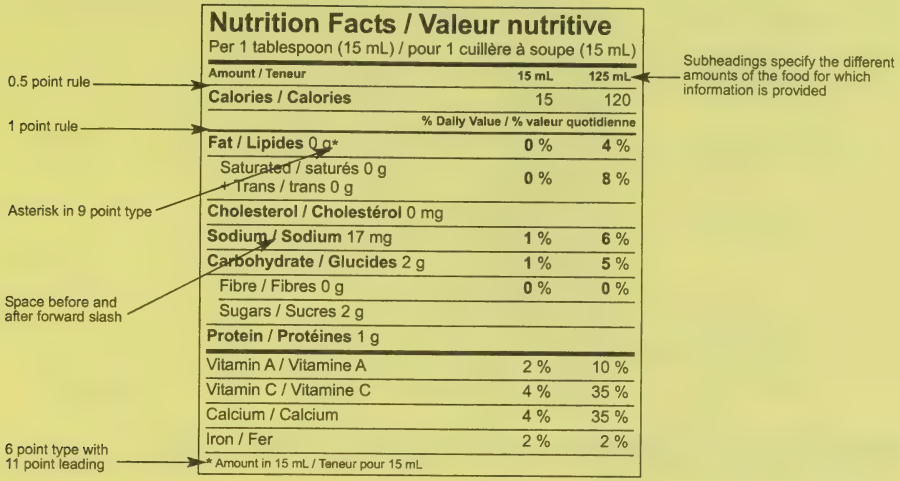
Follow Figures 12.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type; leading for the footnote is reduced by 1 point.

Figures 12.6(E) and (F)

Follow Figures 12.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings, by 3 points where there is a rule, and by 2 points where there is no rule and for the footnote; thin rules are reduced to 0.25 point.

Bilingual Dual Format – Different Amounts of Food

Figure 13.1(B)



Nutrition Facts / Valeur nutritive

Per 1 tablespoon (15 mL) / pour 1 cuillère à soupe (15 mL)

Amount / Teneur	15 mL	125 mL
Calories / Calories	15	120
	% Daily Value / % valeur quotidienne	
Fat / Lipides 0 g*	**0 %**	**4 %**
Saturated / saturés 0 g + Trans / trans 0 g	**0 %**	**8 %**
Cholesterol / Cholestérol 0 mg		
Sodium / Sodium 17 mg	**1 %**	**6 %**
Carbohydrate / Glucides 2 g	**1 %**	**5 %**
Fibre / Fibres 0 g	**0 %**	**0 %**
Sugars / Sucres 2 g		
Protein / Protéines 1 g		
Vitamin A / Vitamine A	2 %	10 %
Vitamin C / Vitamine C	4 %	35 %
Calcium / Calcium	4 %	35 %
Iron / Fer	2 %	2 %

* Amount in 15 mL / Teneur pour 15 mL

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.
French terms may appear first.

Figure 13.2(B)

Follow Figure 13.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 13.3(B)

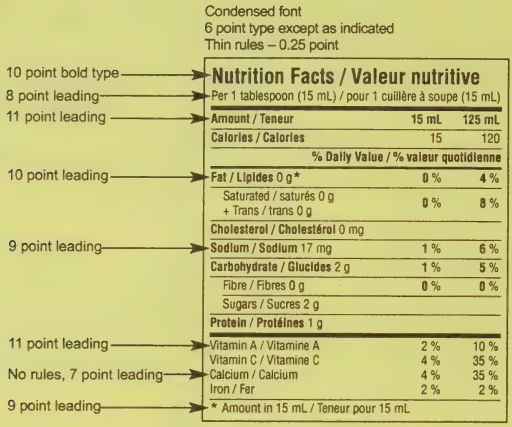
Follow Figure 13.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 13.4(B)

Follow Figure 13.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type; leading for the footnote is reduced by 1 point.

Bilingual Dual Format – Different Amounts of Food (*continued*)

Figure 13.5(B)



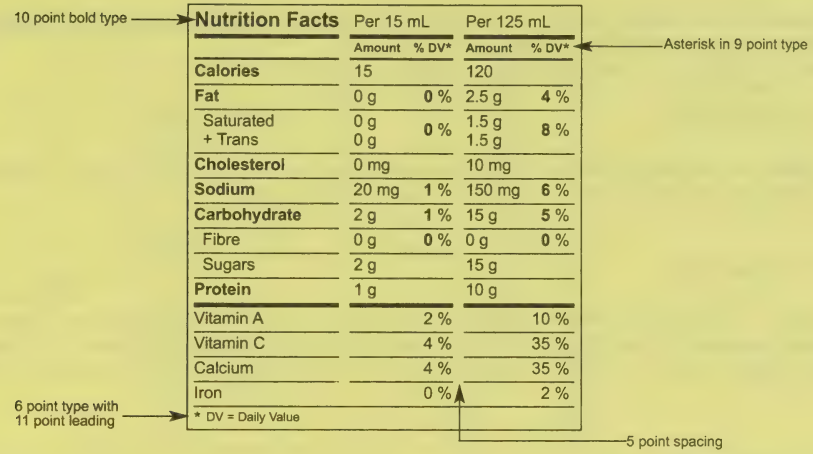
Note: Same format specifications as in Figure 13.1(B) except as otherwise indicated.
French terms may appear first.

Figure 13.6(B)

Follow Figure 13.5(B) except: leading is reduced by 1 point where there is a rule.

Aggregate Format – Different Amounts of Food

Figure 14.1(E)

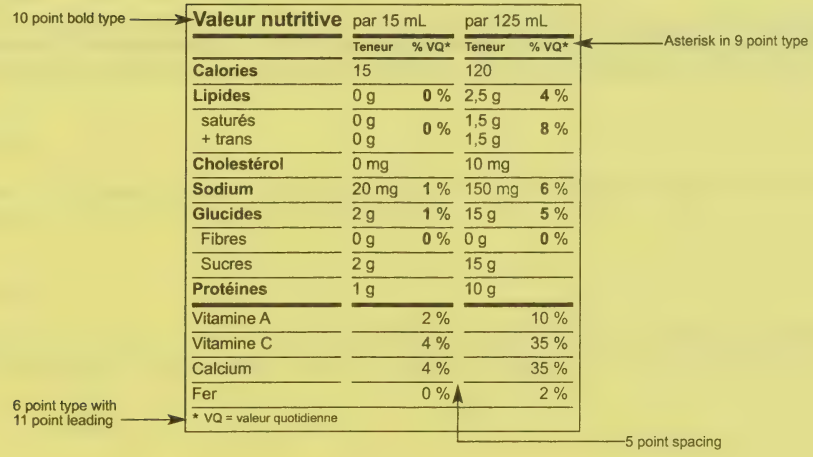


Nutrition Facts	Per 15 mL		Per 125 mL	
	Amount	% DV*	Amount	% DV*
Calories	15		120	
Fat	0 g	**0** %	2.5 g	**4** %
Saturated + Trans	0 g 0 g	**0** %	1.5 g 1.5 g	**8** %
Cholesterol	0 mg		10 mg	
Sodium	20 mg	**1** %	150 mg	**6** %
Carbohydrate	2 g	**1** %	15 g	**5** %
Fibre	0 g	**0** %	0 g	**0** %
Sugars	2 g		15 g	
Protein	1 g		10 g	
Vitamin A		2 %		10 %
Vitamin C		4 %		35 %
Calcium		4 %		35 %
Iron		0 %		2 %

* DV = Daily Value

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 14.1(F)



Valeur nutritive	par 15 mL		par 125 mL	
	Teneur	% VQ*	Teneur	% VQ*
Calories	15		120	
Lipides	0 g	**0** %	2,5 g	**4** %
saturés + trans	0 g 0 g	**0** %	1,5 g 1,5 g	**8** %
Cholestérol	0 mg		10 mg	
Sodium	20 mg	**1** %	150 mg	**6** %
Glucides	2 g	**1** %	15 g	**5** %
Fibres	0 g	**0** %	0 g	**0** %
Sucres	2 g		15 g	
Protéines	1 g		10 g	
Vitamine A		2 %		10 %
Vitamine C		4 %		35 %
Calcium		4 %		35 %
Fer		0 %		2 %

* VQ = valeur quotidienne

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Aggregate Format – Different Amounts of Food (*continued*)

Figures 14.2(E) and (F)

Follow Figures 14.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 14.3(E) and (F)

Follow Figures 14.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 14.4(E) and (F)

Follow Figures 14.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type; leading is reduced by 1 point for subheadings and the footnote, by 2 points where there is a rule, and by 1 point where there is no rule; thin rules are reduced to 0.25 point.

Figures 14.5(E) and (F)

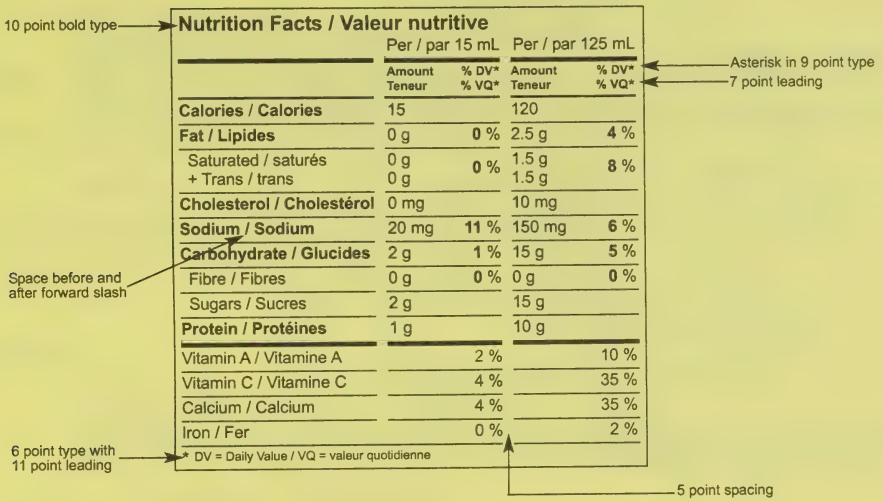
Follow Figures 14.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; leading for the footnote is reduced by 1 point.

Figures 14.6(E) and (F)

Follow Figures 14.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type; leading is reduced by 1 point for subheadings, by 3 points where there is a rule, and by 2 points where there is no rule and for the footnote; thin rules are reduced to 0.25 point.

Bilingual Aggregate Format – Different Amounts of Food

Figure 15.1(B)



Nutrition Facts / Valeur nutritive

	Per / par 15 mL		Per / par 125 mL	
	Amount Teneur	% DV* % VQ*	Amount Teneur	% DV* % VQ*
Calories / Calories	15		120	
Fat / Lipides	0 g	**0 %**	2.5 g	**4 %**
Saturated / saturés + Trans / trans	0 g 0 g	**0 %**	1.5 g 1.5 g	**8 %**
Cholesterol / Cholestérol	0 mg		10 mg	
Sodium / Sodium	20 mg	**11 %**	150 mg	**6 %**
Carbohydrate / Glucides	2 g	**1 %**	15 g	**5 %**
Fibre / Fibres	0 g	**0 %**	0 g	**0 %**
Sugars / Sucres	2 g		15 g	
Protein / Protéines	1 g		10 g	
Vitamin A / Vitamine A		2 %		10 %
Vitamin C / Vitamine C		4 %		35 %
Calcium / Calcium		4 %		35 %
Iron / Fer		0 %		2 %

* DV = Daily Value / VQ = valeur quotidienne

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.
French terms may appear first.

Figure 15.2(B)

Follow Figure 15.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 15.3(B)

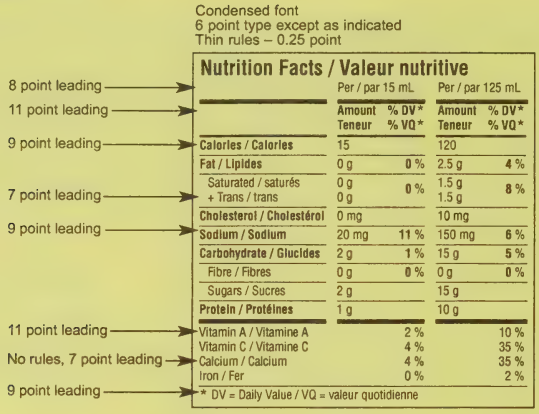
Follow Figure 15.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 15.4(B)

Follow Figure 15.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; leading for the footnote is reduced by 1 point.

Bilingual Aggregate Format – Different Amounts of Food (*continued*)

Figure 15.5(B)



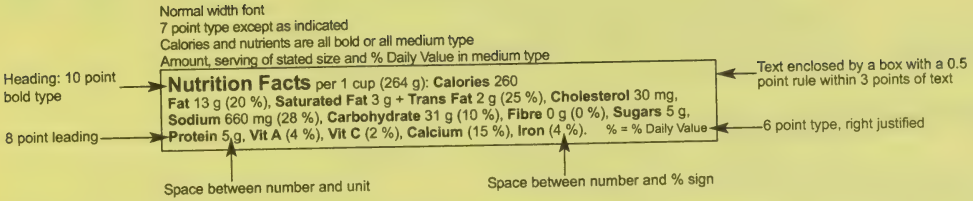
Note: Same format specifications as in Figure 15.1(B) except as otherwise indicated.
French terms may appear first.

Figure 15.6(B)

Follow Figure 15.5(B) except: leading is reduced by 1 point where there is a rule.

Linear Format

Figure 16.1(E)



Note: Number of lines may vary according to available display surface.
Texts of Figures 16.1(E) and (F) may be displayed adjacent to one another within the same box.

Figure 16.1(F)

Valeur nutritive pour 1 tasse (264 g) : **Calories** 260
Lipides 13 g (20 %), **Lipides saturés** 3 g + **Lipides trans** 2 g (25 %), **Cholestérol** 30 mg,
Sodium 660 mg (28 %), **Glucides** 31 g (10 %), **Fibres** 0 g (0 %), **Sucres** 5 g, **Protéines** 5 g,
Vit A (4 %), **Vit C** (2 %), **Calcium** (15 %), **Fer** (4 %). % = % valeur quotidienne

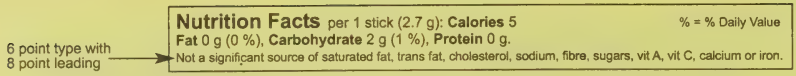
Note: Same format specifications as in Figure 16.1(E).

Figures 16.2(E) and (F)

Follow Figures 16.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 1 point.

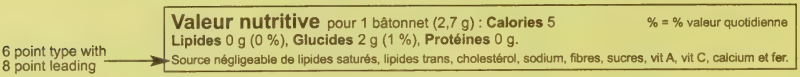
Simplified Linear Format

Figure 17.1(E)



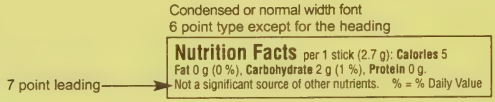
Note: Same format specifications as in Figure 16.1(E) except as otherwise indicated.

Figure 17.1(F)



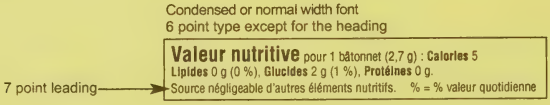
Note: Same format specifications as in Figure 16.1(E) except as otherwise indicated.

Figure 17.2(E)



Note: Same format specifications as in Figure 17.1(E) except as otherwise indicated.

Figure 17.2(F)

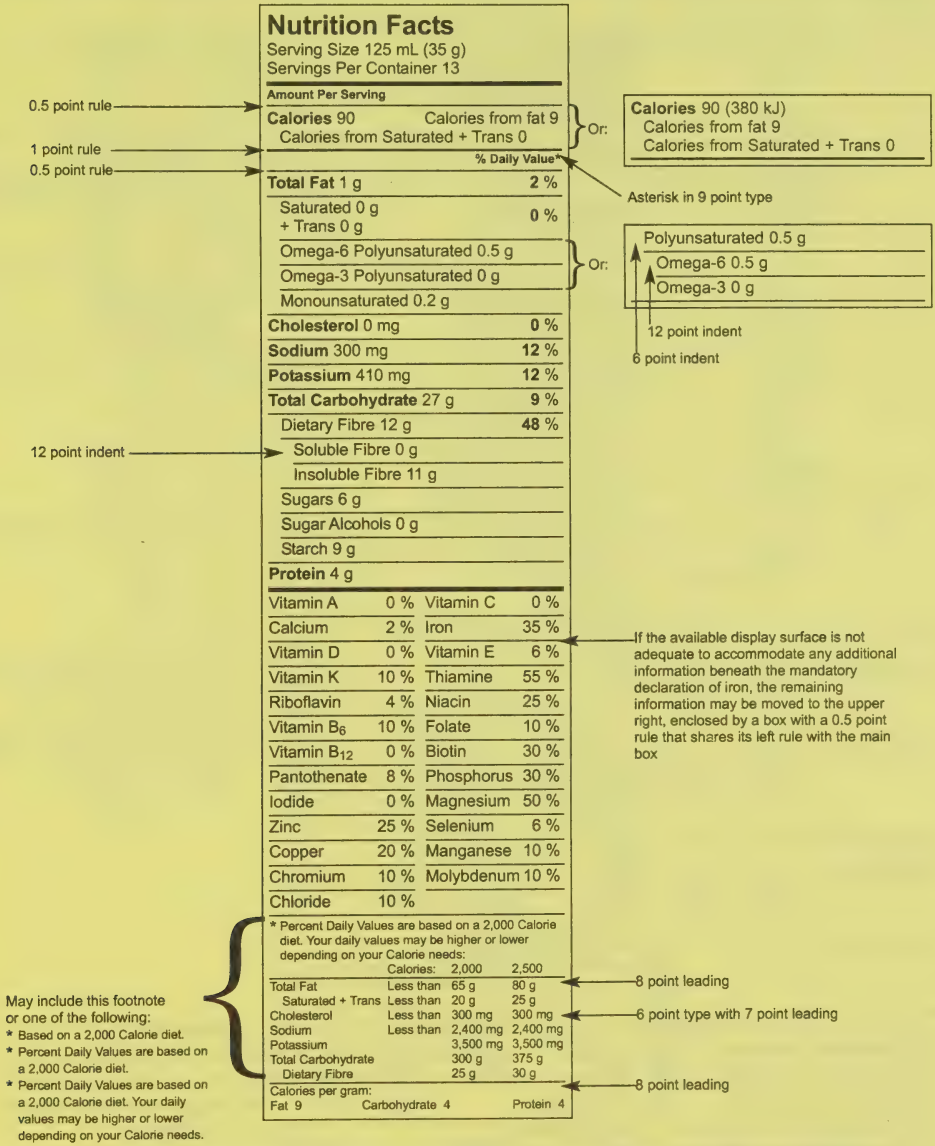


Note: Same format specifications as in Figure 17.1(E) except as otherwise indicated.

Presentation of Additional Information

Including all optional elements that may be declared in the nutrition facts table

Figure 18.1(E) See tables to sections B.01.401 and B.01.402 for wording alternatives

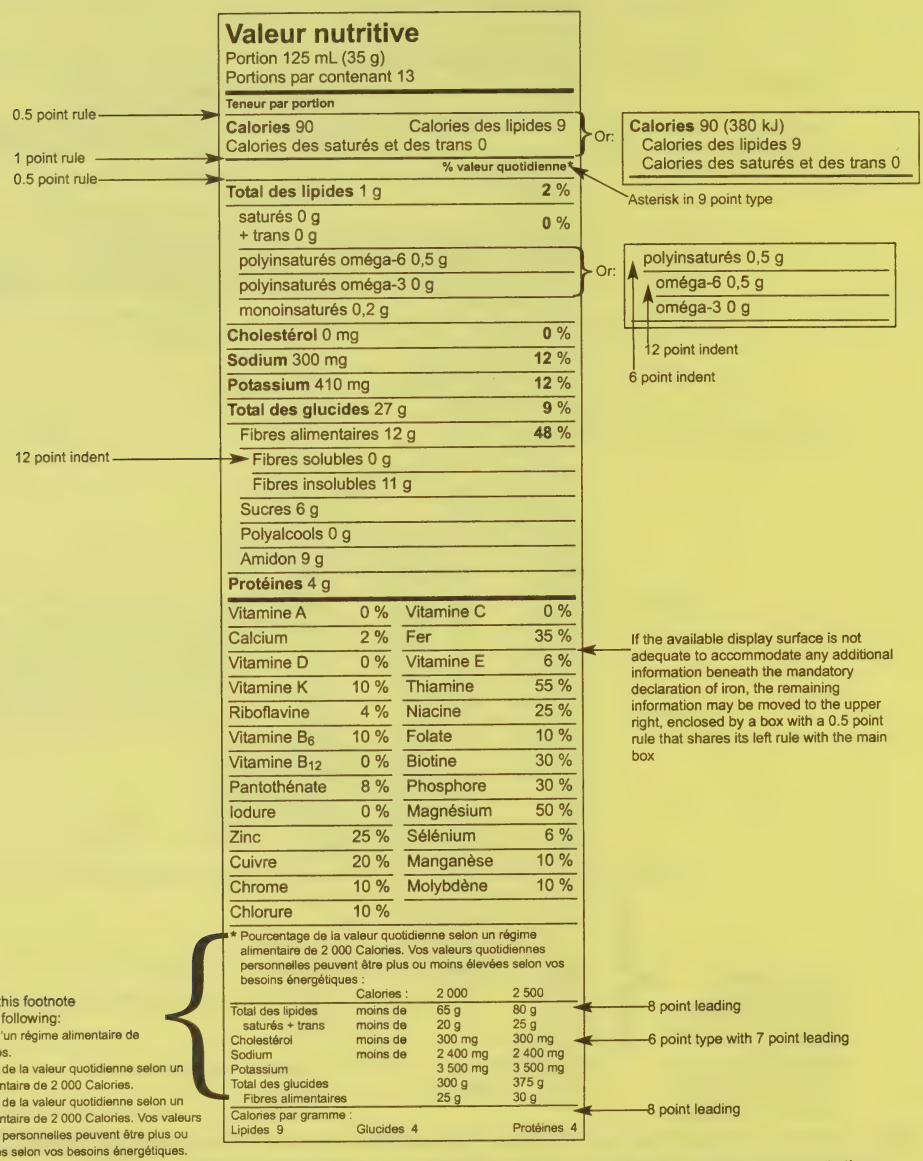


Note: In respect of matters other than the order of presentation, the use of indents and the presentation of footnotes, follow the format that is specified in the applicable figure of this Schedule.

Presentation of Additional Information (*continued*)

Including all optional elements that may be declared in the nutrition facts table

Figure 18.1(F) See tables to sections B.01.401 and B.01.402 for wording alternatives

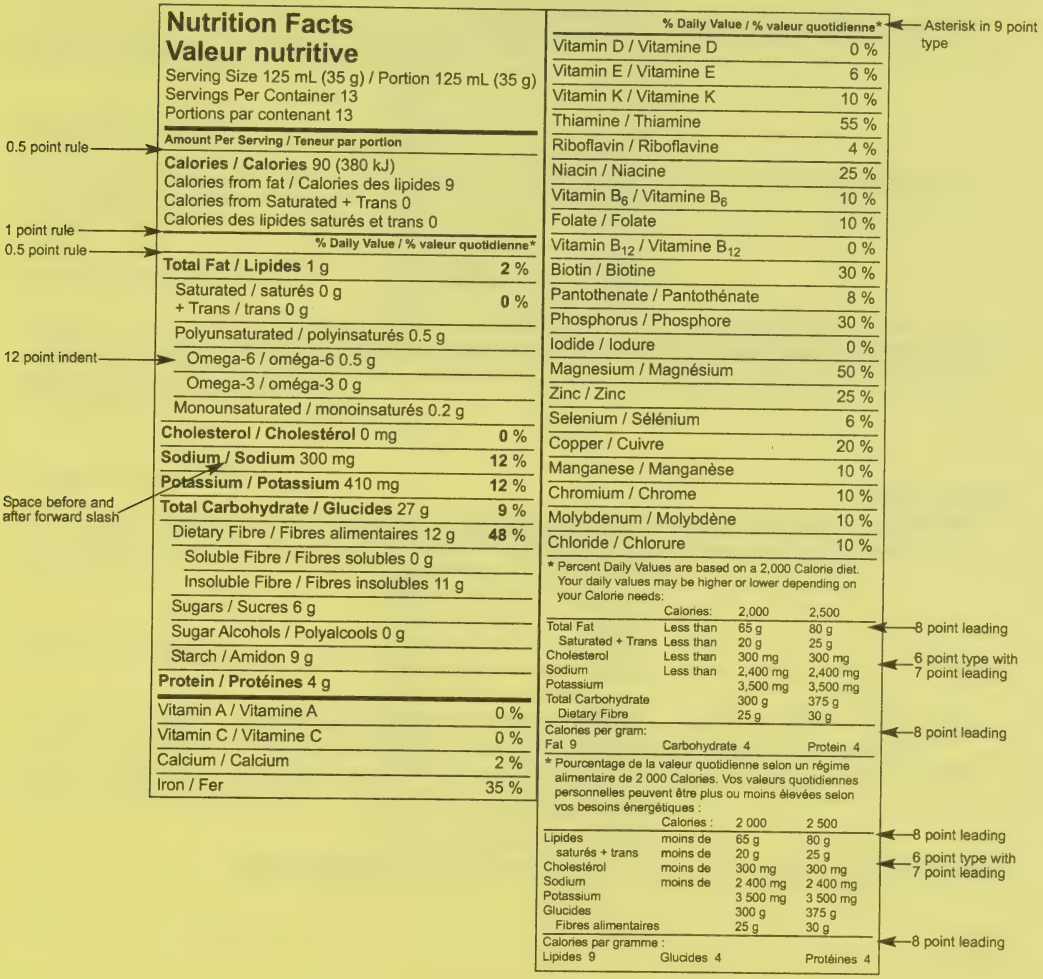


Note: In respect of matters other than the order of presentation, the use of indents and the presentation of footnotes, follow the format that is specified in the applicable figure of this Schedule.

Bilingual Presentation of Additional Information

Including all optional elements that may be declared in the nutrition facts table

Figure 19.1(B) See tables to sections B.01.401 and B.01.402 for wording alternatives



Nutrition Facts
Valeur nutritive

Serving Size 125 mL (35 g) / Portion 125 mL (35 g)
Servings Per Container 13
Portions par contenant 13

0.5 point rule

Amount Per Serving / Teneur par portion

Calories / Calories 90 (380 kJ)
Calories from fat / Calories des lipides 9
Calories from Saturated + Trans 0
Calories des lipides saturés et trans 0

1 point rule

0.5 point rule

% Daily Value / % valeur quotidienne*

Total Fat / Lipides 1 g	**2 %**
Saturated / saturés 0 g + Trans / trans 0 g	**0 %**
Polyunsaturated / polyinsaturés 0.5 g	
12 point indent — Omega-6 / oméga-6 0.5 g	
Omega-3 / oméga-3 0 g	
Monounsaturated / monoinsaturés 0.2 g	
Cholesterol / Cholestérol 0 mg	**0 %**
Sodium / Sodium 300 mg	**12 %**
Potassium / Potassium 410 mg	**12 %**
Total Carbohydrate / Glucides 27 g	**9 %**
Dietary Fibre / Fibres alimentaires 12 g	**48 %**
Soluble Fibre / Fibres solubles 0 g	
Insoluble Fibre / Fibres insolubles 11 g	
Sugars / Sucres 6 g	
Sugar Alcohols / Polyalcools 0 g	
Starch / Amidon 9 g	
Protein / Protéines 4 g	

Space before and after forward slash

Vitamin A / Vitamine A	0 %
Vitamin C / Vitamine C	0 %
Calcium / Calcium	2 %
Iron / Fer	35 %

% Daily Value / % valeur quotidienne*	
Vitamin D / Vitamine D	0 %
Vitamin E / Vitamine E	6 %
Vitamin K / Vitamine K	10 %
Thiamine / Thiamine	55 %
Riboflavin / Riboflavine	4 %
Niacin / Niacine	25 %
Vitamin B_6 / Vitamine B_6	10 %
Folate / Folate	10 %
Vitamin B_{12} / Vitamine B_{12}	0 %
Biotin / Biotine	30 %
Pantothenate / Pantothénate	8 %
Phosphorus / Phosphore	30 %
Iodide / Iodure	0 %
Magnesium / Magnésium	50 %
Zinc / Zinc	25 %
Selenium / Sélénium	6 %
Copper / Cuivre	20 %
Manganese / Manganèse	10 %
Chromium / Chrome	10 %
Molybdenum / Molybdène	10 %
Chloride / Chlorure	10 %

Asterisk in 9 point type

* Percent Daily Values are based on a 2,000 Calorie diet. Your daily values may be higher or lower depending on your Calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65 g	80 g
Saturated + Trans	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2,400 mg	2,400 mg
Potassium		3,500 mg	3,500 mg
Total Carbohydrate		300 g	375 g
Dietary Fibre		25 g	30 g

8 point leading

6 point type with 7 point leading

Calories per gram:
Fat 9 Carbohydrate 4 Protein 4

8 point leading

* Pourcentage de la valeur quotidienne selon un régime alimentaire de 2 000 Calories. Vos valeurs quotidiennes personnelles peuvent être plus ou moins élevées selon vos besoins énergétiques :

	Calories :	2 000	2 500
Lipides	moins de	65 g	80 g
saturés + trans	moins de	20 g	25 g
Cholestérol	moins de	300 mg	300 mg
Sodium	moins de	2 400 mg	2 400 mg
Potassium		3 500 mg	3 500 mg
Glucides		300 g	375 g
Fibres alimentaires		25 g	30 g

8 point leading

6 point type with 7 point leading

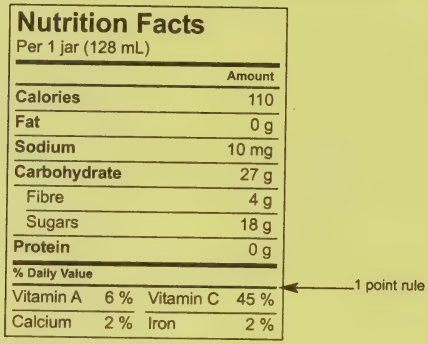
Calories par gramme :
Lipides 9 Glucides 4 Protéines 4

8 point leading

Note: % Daily Value footnote may be replaced by options set out in Figures 18.1(E) and (F).
In respect of matters other than the order of presentation, the use of indents and the presentation of footnotes, follow the format that is specified in the applicable figure of this Schedule.
French terms may appear first.

Standard Format
Children Under Two Years of Age

Figure 20.1(E)



Nutrition Facts
Per 1 jar (128 mL)

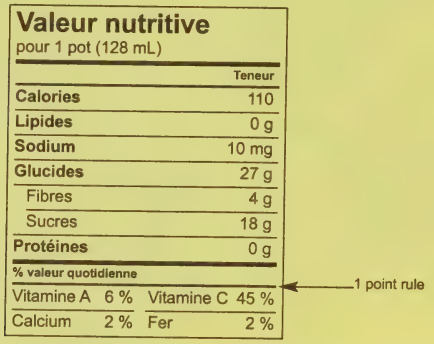
	Amount
Calories	110
Fat	0 g
Sodium	10 mg
Carbohydrate	27 g
Fibre	4 g
Sugars	18 g
Protein	0 g

% Daily Value			
Vitamin A	6 %	Vitamin C	45 %
Calcium	2 %	Iron	2 %

1 point rule

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 20.1(F)



Valeur nutritive
pour 1 pot (128 mL)

	Teneur
Calories	110
Lipides	0 g
Sodium	10 mg
Glucides	27 g
Fibres	4 g
Sucres	18 g
Protéines	0 g

% valeur quotidienne			
Vitamine A	6 %	Vitamine C	45 %
Calcium	2 %	Fer	2 %

1 point rule

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Standard Format
Children Under Two Years of Age (*continued*)

Figures 20.2(E) and (F)

Follow Figures 20.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 20.3(E) and (F)

Follow Figures 20.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 20.4(E) and (F)

Follow Figures 20.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings, by 2 points where there is a rule and by 1 point where there is no rule; thin rules are reduced to 0.25 point.

Figures 20.5(E) and (F)

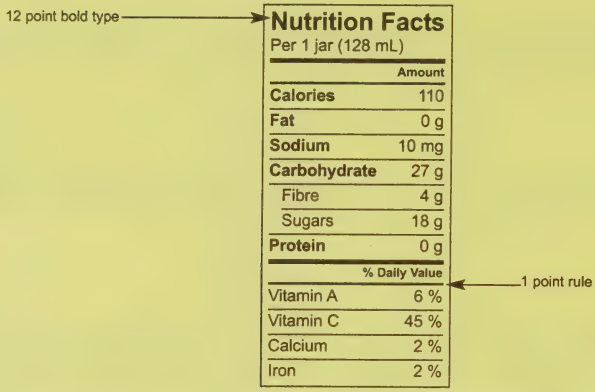
Follow Figures 20.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type.

Figures 20.6(E) and (F)

Follow Figures 20.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type and the heading in 10 point bold type; leading is reduced by 1 point for subheadings, by 3 points where there is a rule and by 2 points where there is no rule; thin rules are reduced to 0.25 point.

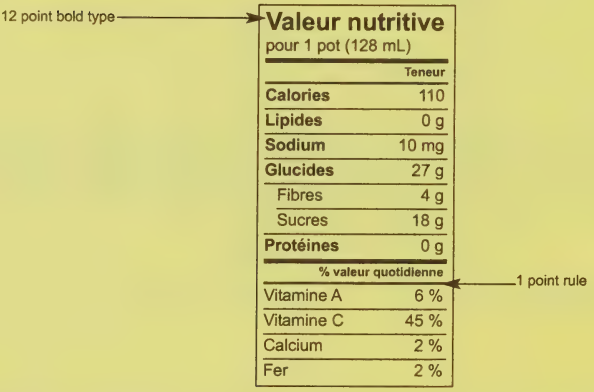
Narrow Standard Format
Children Under Two Years of Age

Figure 21.1(E)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 21.1(F)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Narrow Standard Format
Children Under Two Years of Age (*continued*)

Figures 21.2(E) and (F)

Follow Figures 21.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point; the heading is diplayed in 11 point bold type.

Figures 21.3(E) and (F)

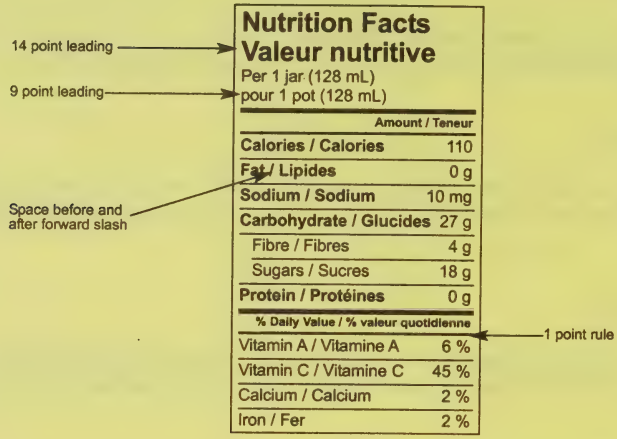
Follow Figures 21.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point; the heading is diplayed in 10 point bold type.

Figures 21.4(E) and (F)

Follow Figures 21.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type.

Bilingual Standard Format
Children Under Two Years of Age

Figure 22.1(B)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.
French terms may appear first.

Figure 22.2(B)

Follow Figure 22.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 22.3(B)

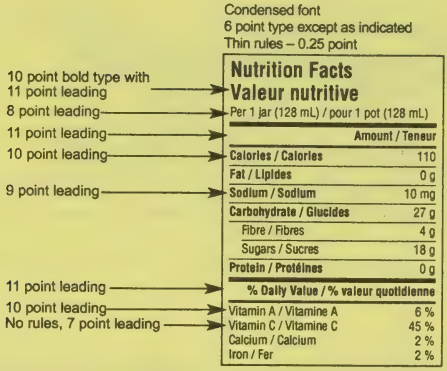
Follow Figure 22.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 22.4(B)

Follow Figure 22.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type with leading reduced by 3 points.

Bilingual Standard Format
Children Under Two Years of Age (*continued*)

Figure 22.5(B)



Note: Same format specifications as in Figure 22.1(B) except as otherwise indicated.
French terms may appear first.

Figure 22.6(B)

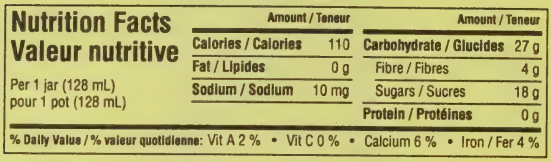
Follow Figure 22.5(B) except: leading is reduced by 1 point where there is a rule.

Figure 22.7(B)

Follow Figure 22.5(B) except: the heading may be displayed in 9 point bold type with leading reduced by 3 points; leading may be reduced by 2 points where there is a rule, and by 1 point where there is no rule except for subheadings; box enclosing text may be displayed with a 0.25 point rule within 1 point of text; 2 point rules may be reduced to 1.5 points and the 1 point rule may be reduced to 0.75 point.

Bilingual Horizontal Format
Children Under Two Years of Age

Figure 23.1(B)



Nutrition Facts / Valeur nutritive	Amount / Teneur		Amount / Teneur
Per 1 jar (128 mL) / pour 1 pot (128 mL)	Calories / Calories 110	Carbohydrate / Glucides	27 g
	Fat / Lipides 0 g	Fibre / Fibres	4 g
	Sodium / Sodium 10 mg	Sugars / Sucres	18 g
		Protein / Protéines	0 g

% Daily Value / % valeur quotidienne: Vit A 2 % • Vit C 0 % • Calcium 6 % • Iron / Fer 4 %

Note: Same format specifications as in Figure 4.1(B).
French terms may appear first.

Figure 23.2(B)

Follow Figure 23.1(B) except: serving of stated size, Calories and nutrients are displayed in 6 point type; the heading is displayed in 10 point bold type with leading reduced by 3 points; leading is reduced by 1 point in the right column and the information in the other columns is adjusted accordingly.

Figure 23.3(B)

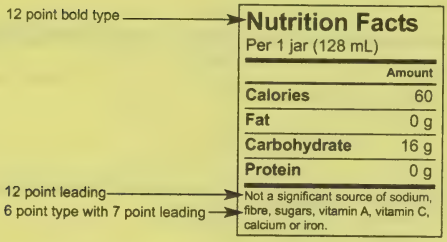
Follow Figure 23.1(B) except: serving of stated size, Calories and nutrients are displayed in 6 point type; the heading is displayed in 10 point bold type with leading reduced by 3 points; leading is reduced by 2 points in the right column and the information in the other columns is adjusted accordingly; thin rules are reduced to 0.25 point.

Figure 23.4(B)

Follow Figure 23.1(B) except: serving of stated size, Calories and nutrients are displayed in 6 point type; the heading is displayed in 10 point bold type with leading reduced by 3 points; leading is reduced by 3 points in the right column and the information in the other columns is adjusted accordingly; thin rules are reduced to 0.25 point.

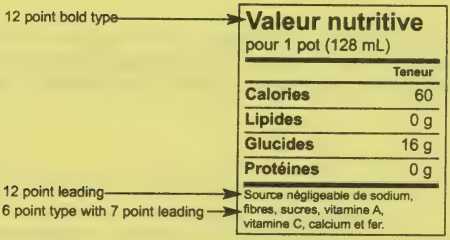
Simplified Standard Format
Children Under Two Years of Age

Figure 24.1(E)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 24.1(F)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Simplified Standard Format
Children Under Two Years of Age (*continued*)

Figures 24.2(E) and (F)

Follow Figures 24.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 24.3(E) and (F)

Follow Figures 24.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 24.4(E) and (F)

Follow Figures 24.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type and the heading in 10 point bold type; leading is reduced by 1 point for the subheading, by 2 points where there is a rule, and by 1 point where there is no rule, except for the footnote; thin rules are reduced to 0.25 point.

Figures 24.5(E) and (F)

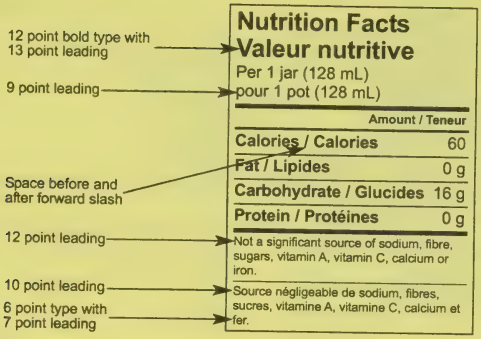
Follow Figures 24.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type.

Figures 24.6(E) and (F)

Follow Figures 24.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type and the heading in 10 point bold type; leading is reduced by 1 point for the subheading, by 3 points where there is a rule, and by 2 points where there is no rule, except for the footnote; thin rules are reduced to 0.25 point.

Bilingual Simplified Standard Format
Children Under Two Years of Age

Figure 25.1(B)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated. French terms may appear first.

Figure 25.2(B)

Follow Figure 25.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 25.3(B)

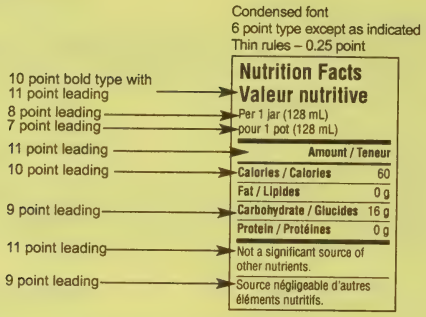
Follow Figure 25.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 25.4(B)

Follow Figure 25.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; the heading is displayed in 10 point bold type with leading reduced by 3 points.

Bilingual Simplified Standard Format
Children Under Two Years of Age (*continued*)

Figure 25.5(B)



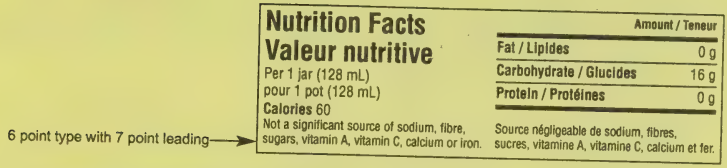
Note: Same format specifications as in Figure 25.1(B) except as otherwise indicated.
French terms may appear first.

Figure 25.6(B)

Follow Figure 25.5(B) except: leading is reduced by 1 point where there is a rule.

Bilingual Simplified Horizontal Format
Children Under Two Years of Age

Figure 26.1(B)

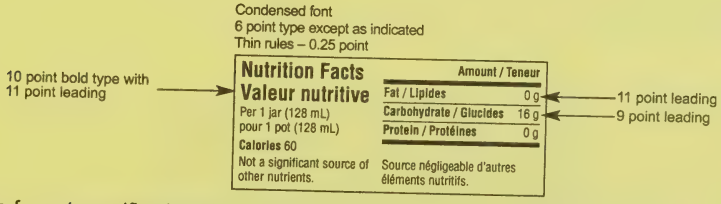


Note: Same format specifications as in Figure 4.1(B) except as otherwise indicated.
French terms may appear first.

Figure 26.2(B)

Follow Figure 26.1(B) except: serving of stated size, Calories and nutrients are displayed in 6 point type; the heading is displayed in 10 point bold type with leading reduced by 3 points; leading is reduced by 1 point where there is a rule and the information in the other column is adjusted accordingly.

Figure 26.3(B)



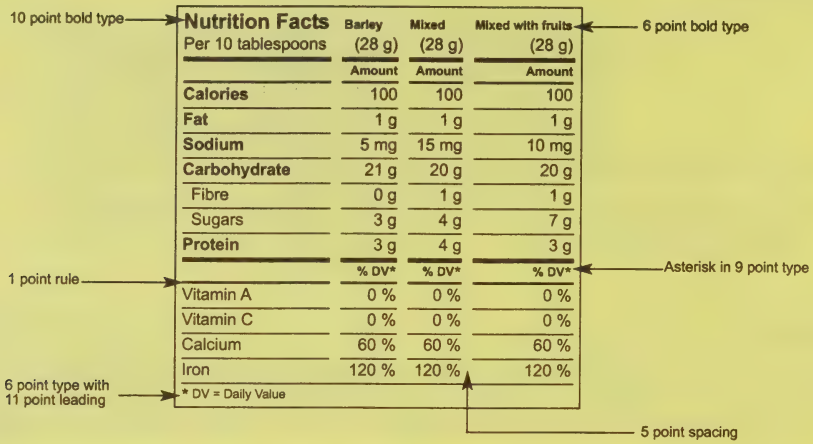
Note: Same format specifications as in Figure 26.1(B) except as otherwise indicated.
French terms may appear first.

Figure 26.4(B)

Follow Figure 26.3(B) except: leading is reduced by 1 point where there is a rule and the information in the other column is adjusted accordingly.

Aggregate Format – Different Kinds of Foods Children Under Two Years of Age

Figure 27.1(E)

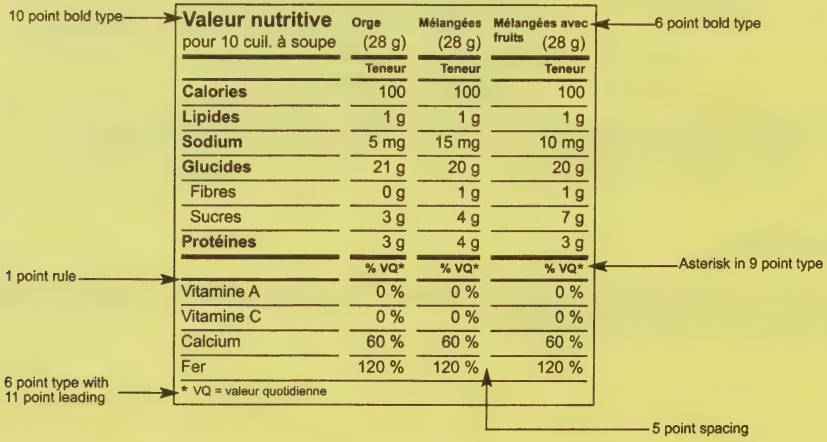


Nutrition Facts Per 10 tablespoons	Barley (28 g)	Mixed (28 g)	Mixed with fruits (28 g)
	Amount	Amount	Amount
Calories	100	100	100
Fat	1 g	1 g	1 g
Sodium	5 mg	15 mg	10 mg
Carbohydrate	21 g	20 g	20 g
Fibre	0 g	1 g	1 g
Sugars	3 g	4 g	7 g
Protein	3 g	4 g	3 g
	% DV*	% DV*	% DV*
Vitamin A	0 %	0 %	0 %
Vitamin C	0 %	0 %	0 %
Calcium	60 %	60 %	60 %
Iron	120 %	120 %	120 %

* DV = Daily Value

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 27.1(F)



Valeur nutritive pour 10 cuil. à soupe	Orge (28 g)	Mélangées (28 g)	Mélangées avec fruits (28 g)
	Teneur	Teneur	Teneur
Calories	100	100	100
Lipides	1 g	1 g	1 g
Sodium	5 mg	15 mg	10 mg
Glucides	21 g	20 g	20 g
Fibres	0 g	1 g	1 g
Sucres	3 g	4 g	7 g
Protéines	3 g	4 g	3 g
	% VQ*	% VQ*	% VQ*
Vitamine A	0 %	0 %	0 %
Vitamine C	0 %	0 %	0 %
Calcium	60 %	60 %	60 %
Fer	120 %	120 %	120 %

* VQ = valeur quotidienne

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Aggregate Format – Different Kinds of Foods Children Under Two Years of Age (*continued*)

Figures 27.2(E) and (F)

Follow Figures 27.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 27.3(E) and (F)

Follow Figures 27.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 27.4(E) and (F)

Follow Figures 27.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type; leading is reduced by 1 point for subheadings and the footnote, by 2 points where there is a rule, and by 1 point where there is no rule; thin rules are reduced to 0.25 point.

Figures 27.5(E) and (F)

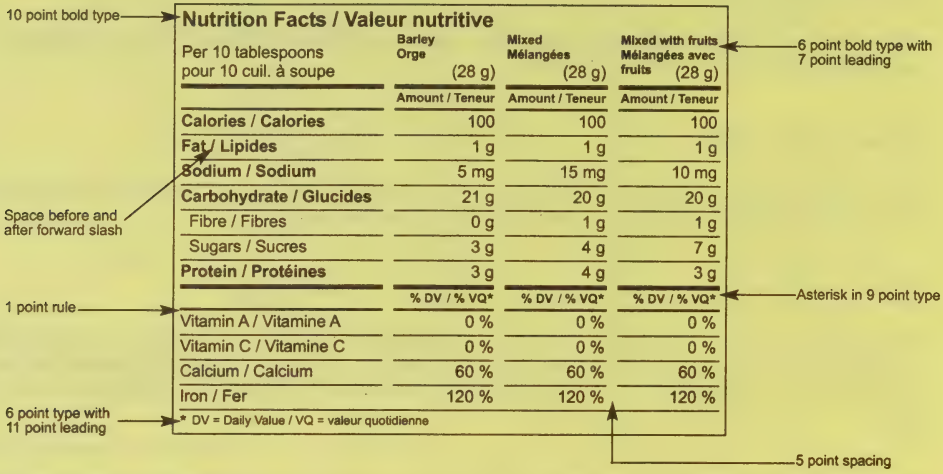
Follow Figures 27.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; leading for the footnote is reduced by 1 point.

Figures 27.6(E) and (F)

Follow Figures 27.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type; leading is reduced by 1 point for subheadings, by 3 points where there is a rule, and by 2 points where there is no rule and for the footnote; thin rules are reduced to 0.25 point.

Bilingual Aggregate Format – Different Kinds of Foods Children Under Two Years of Age

Figure 28.1(B)



Nutrition Facts / Valeur nutritive

Per 10 tablespoons / pour 10 cuil. à soupe	Barley / Orge (28 g)	Mixed / Mélangées (28 g)	Mixed with fruits / Mélangées avec fruits (28 g)
	Amount / Teneur	Amount / Teneur	Amount / Teneur
Calories / Calories	100	100	100
Fat / Lipides	1 g	1 g	1 g
Sodium / Sodium	5 mg	15 mg	10 mg
Carbohydrate / Glucides	21 g	20 g	20 g
Fibre / Fibres	0 g	1 g	1 g
Sugars / Sucres	3 g	4 g	7 g
Protein / Protéines	3 g	4 g	3 g
	% DV / % VQ*	% DV / % VQ*	% DV / % VQ*
Vitamin A / Vitamine A	0 %	0 %	0 %
Vitamin C / Vitamine C	0 %	0 %	0 %
Calcium / Calcium	60 %	60 %	60 %
Iron / Fer	120 %	120 %	120 %

* DV = Daily Value / VQ = valeur quotidienne

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.
French terms may appear first.

Figure 28.2(B)

Follow Figure 28.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 28.3(B)

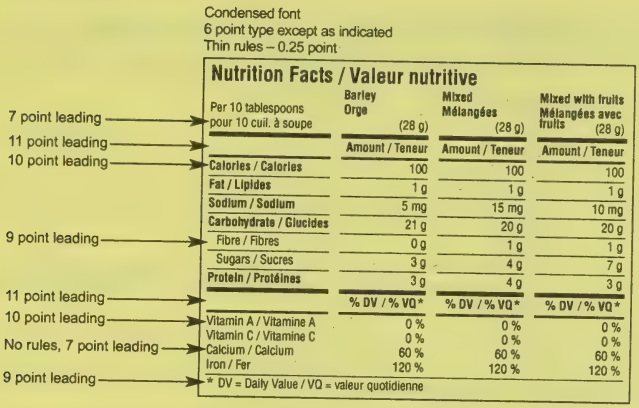
Follow Figure 28.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 28.4(B)

Follow Figure 28.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; leading for the footnote is reduced by 1 point.

Bilingual Aggregate Format – Different Kinds of Foods Children Under Two Years of Age (*continued*)

Figure 28.5(B)



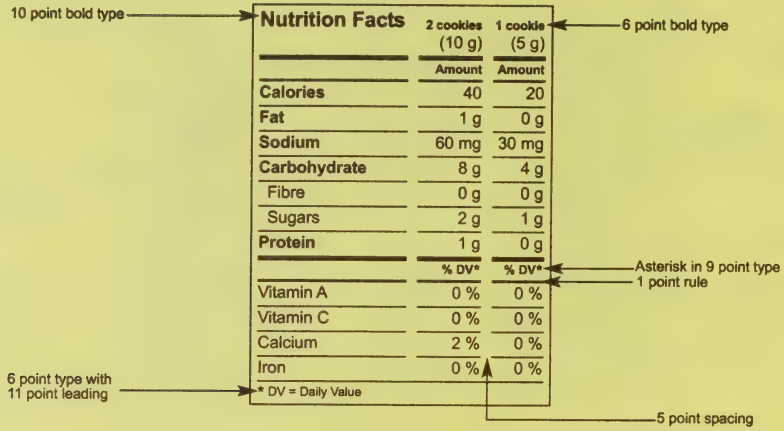
Note: Same format specifications as in Figure 28.1(B) except as otherwise indicated. French terms may appear first.

Figure 28.6(B)

Follow Figure 28.5(B) except: leading is reduced by 1 point where there is a rule.

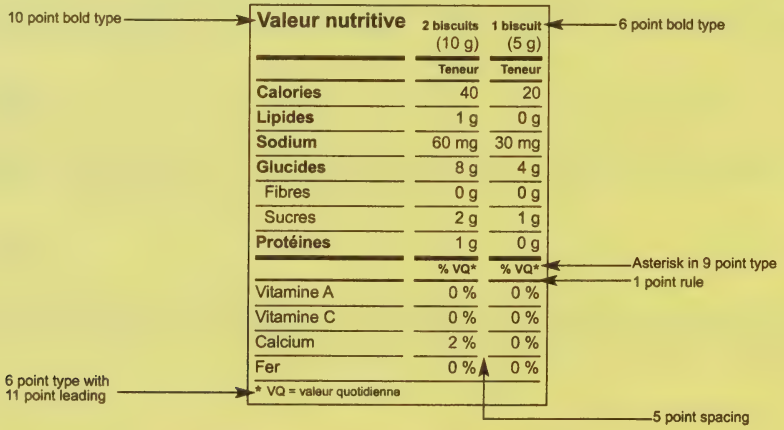
Aggregate Format – Different Amounts of Food Children Under Two Years of Age

Figure 29.1(E)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Figure 29.1(F)



Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.

Aggregate Format – Different Amounts of Food Children Under Two Years of Age (*continued*)

Figures 29.2(E) and (F)

Follow Figures 29.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 29.3(E) and (F)

Follow Figures 29.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figures 29.4(E) and (F)

Follow Figures 29.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type; leading is reduced by 1 point for subheadings and the footnote, by 2 points where there is a rule, and by 1 point where there is no rule; thin rules are reduced to 0.25 point.

Figures 29.5(E) and (F)

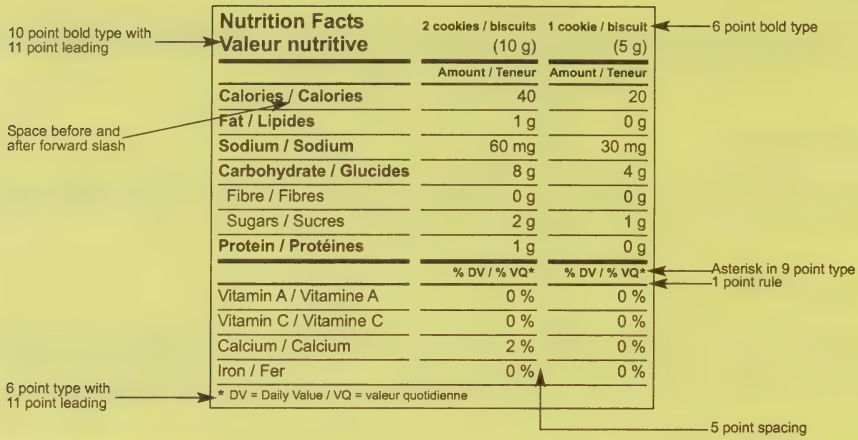
Follow Figures 29.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; leading for the footnote is reduced by 1 point.

Figures 29.6(E) and (F)

Follow Figures 29.1(E) and (F) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type; leading is reduced by 1 point for subheadings, by 3 points where there is a rule, and by 2 points where there is no rule and for the footnote; thin rules are reduced to 0.25 point.

Bilingual Aggregate Format – Different Amounts of Food Children Under Two Years of Age

Figure 30.1(B)



Nutrition Facts / Valeur nutritive	2 cookies / biscuits (10 g)	1 cookie / biscuit (5 g)
	Amount / Teneur	Amount / Teneur
Calories / Calories	40	20
Fat / Lipides	1 g	0 g
Sodium / Sodium	60 mg	30 mg
Carbohydrate / Glucides	8 g	4 g
Fibre / Fibres	0 g	0 g
Sugars / Sucres	2 g	1 g
Protein / Protéines	1 g	0 g
	% DV / % VQ*	% DV / % VQ*
Vitamin A / Vitamine A	0 %	0 %
Vitamin C / Vitamine C	0 %	0 %
Calcium / Calcium	2 %	0 %
Iron / Fer	0 %	0 %

* DV = Daily Value / VQ = valeur quotidienne

Note: Same format specifications as in Figure 1.1(E) except as otherwise indicated.
French terms may appear first.

Figure 30.2(B)

Follow Figure 30.1(B) except: serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 30.3(B)

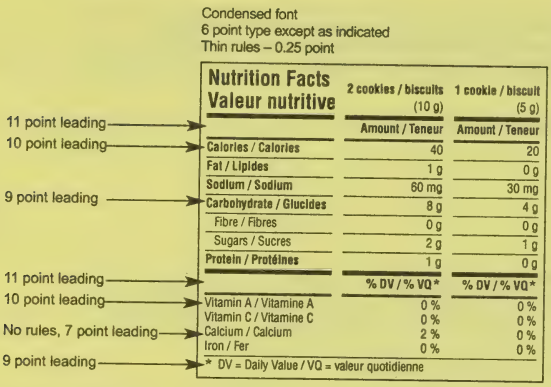
Follow Figure 30.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 7 point type with leading reduced by 1 point.

Figure 30.4(B)

Follow Figure 30.1(B) except: all text is in condensed font; serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 2 points; leading for the footnote is reduced by 1 point.

Bilingual Aggregate Format – Different Amounts of Food Children Under Two Years of Age (*continued*)

Figure 30.5(B)



Note: Same format specifications as in Figure 30.1(B) except as otherwise indicated. French terms may appear first.

Figure 30.6(B)

Follow Figure 30.5(B) except: leading is reduced by 1 point where there is a rule.

Linear Format
Children Under Two Years of Age

Figure 31.1(E)

Nutrition Facts per 1 jar (128 mL): **Calories** 110
Fat 0 g, **Sodium** 10 mg, **Carbohydrate** 27 g, **Fibre** 4 g, **Sugars** 18 g, **Protein** 0 g,
Vit A (6 %), **Vit C** (45 %), **Calcium** (2 %), **Iron** (2 %). % = % Daily Value

Note: Same format specifications as in Figure 16.1(E).

Figure 31.1(F)

Valeur nutritive pour 1 pot (128 mL) : **Calories** 110
Lipides 0 g, **Sodium** 10 mg, **Glucides** 27 g, **Fibres** 4 g, **Sucres** 18 g, **Protéines** 0 g,
Vit A (6 %), **Vit C** (45 %), **Calcium** (2 %), **Fer** (2 %). % = % valeur quotidienne

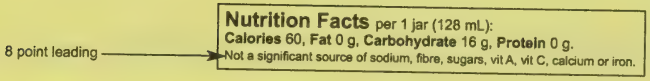
Note: Same format specifications as in Figure 16.1(E).

Figures 31.2(E) and (F)

Follow Figures 31.1(E) and (F) except: serving of stated size, Calories and nutrients are displayed in 6 point type with leading reduced by 1 point.

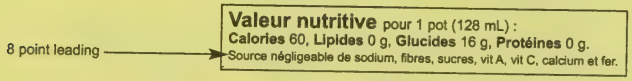
Simplified Linear Format – Children Under Two Years of Age

Figure 32.1(E)



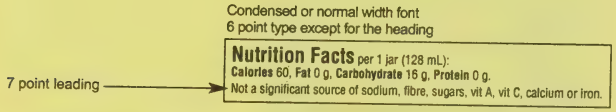
Note: Same format specifications as in Figure 16.1(E) except as otherwise indicated.

Figure 32.1(F)



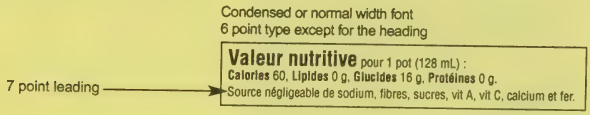
Note: Same format specifications as in Figure 16.1(E) except as otherwise indicated.

Figure 32.2(E)



Note: Same format specifications as in Figure 32.1(E) except as otherwise indicated.

Figure 32.2(F)

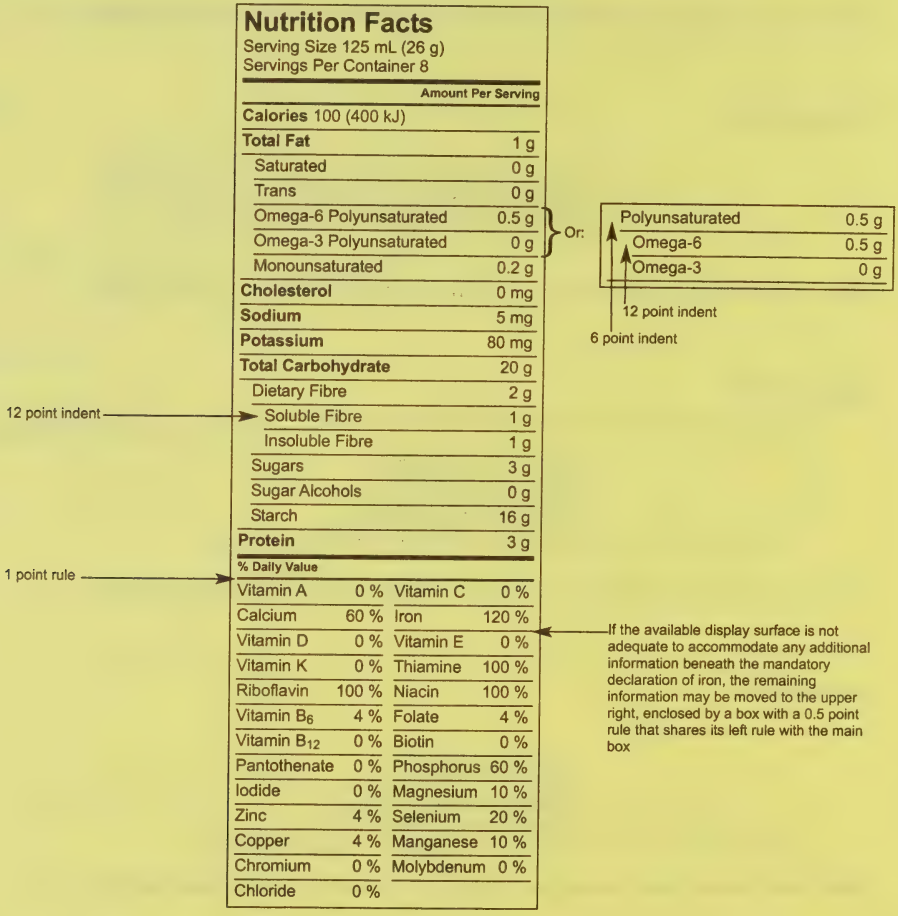


Note: Same format specifications as in Figure 32.1(E) except as otherwise indicated.

Presentation of Additional Information
Children Under Two Years of Age

Including all optional elements that may be declared in the nutrition facts table

Figure 33.1(E) See tables to sections B.01.401 and B.01.402 for wording alternatives

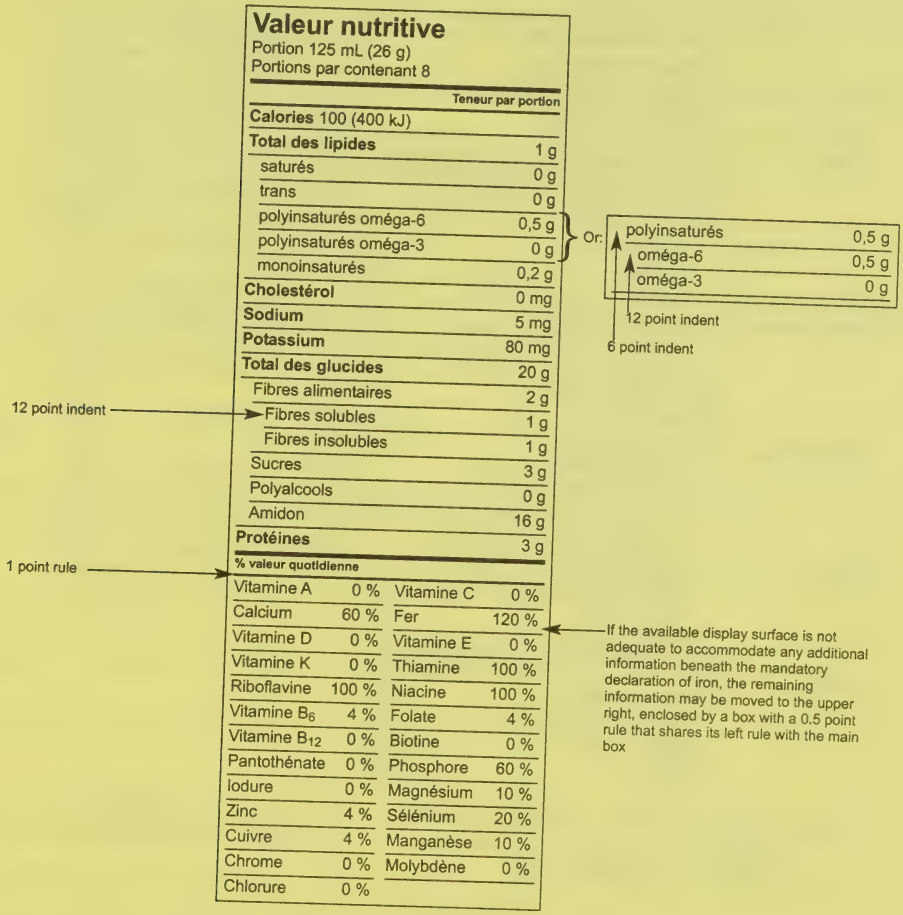


Note: In respect of matters other than the order of presentation, the use of indents and the presentation of footnotes, follow the format that is specified in the applicable figure of this Schedule.

Presentation of Additional Information
Children Under Two Years of Age (*continued*)

Including all optional elements that may be declared in the nutrition facts table

Figure 33.1(F) See tables to sections B.01.401 and B.01.402 for wording alternatives



Note: In respect of matters other than the order of presentation, the use of indents and the presentation of footnotes, follow the format that is specified in the applicable figure of this Schedule.

Bilingual Presentation of Additional Information Children Under Two Years of Age

Including all optional elements that may be declared in the nutrition facts table

Figure 34.1(B) See tables to sections B.01.401 and B.01.402 for wording alternatives

12 point indent

Space before and after forward slash

1 point rule

Nutrition Facts
Valeur nutritive

Serving Size 125 mL (26 g)
Portion 125 mL (26 g)
Servings Per Container 8
Portions par contenant 8

Amount Per Serving / Teneur par portion	
Calories / Calories 100 (400 kJ)	
Total Fat / Lipides	1 g
Saturated / saturés	0 g
Trans / trans	0 g
Polyunsaturated / polyinsaturés	0.5 g
Omega-6 / oméga-6	0.5 g
Omega-3 / oméga-3	0 g
Monounsaturated / monoinsaturés	0.2 g
Cholesterol / Cholestérol	0 mg
Sodium / Sodium	5 mg
Potassium / Potassium	80 mg
Total Carbohydrate / Glucides	21 g
Dietary Fibre / Fibres	2 g
Soluble Fibre / Fibres solubles	1 g
Insoluble Fibre / Fibres insolubles	1 g
Sugars / Sucres	3 g
Sugar Alcohols / Polyalcools	0 g
Starch / Amidon	16 g
Protein / Protéines	3 g

% Daily Value / % valeur quotidienne	
Vitamin A / Vitamine A	0 %
Vitamin C / Vitamine C	0 %
Calcium / Calcium	60 %
Iron / Fer	120 %

% Daily Value / % valeur quotidienne	
Vitamin D / Vitamine D	0 %
Vitamin E / Vitamine E	0 %
Vitamin K / Vitamine K	0 %
Thiamine / Thiamine	100 %
Riboflavin / Riboflavine	100 %
Niacin / Niacine	100 %
Vitamin B_6 / Vitamine B_6	4 %
Folate / Folate	4 %
Vitamin B_{12} / Vitamine B_{12}	0 %
Biotin / Biotine	0 %
Pantothenate / Pantothénate	0 %
Phosphorus / Phosphore	60 %
Iodide / Iodure	0 %
Magnesium / Magnésium	10 %
Zinc / Zinc	4 %
Selenium / Sélénium	20 %
Copper / Cuivre	4 %
Manganese / Manganèse	10 %
Chromium / Chrome	0 %
Molybdenum / Molybdène	0 %
Chloride / Chlorure	0 %

Note: In respect of matters other than the order of presentation, the use of indents and the presentation of footnotes, follow the format that is specified in the applicable figure of this Schedule. French terms may appear first.

Alcoholic Beverages

B.02.001. The foods referred to in this DIVISION are included in the term *alcoholic beverage*.

B.02.002. In this Division,

"**absolute alcohol**" means alcohol of a strength of 100 per cent; (*alcool absolu*)
"**age**" means the period during which an alcoholic beverage is kept under such conditions of storage as may be necessary to develop its characteristic flavour and bouquet; (*âge*)
"**alcohol**" means ethyl alcohol; (alcool)
"**flavouring**" means, in respect of a spirit, any other spirit or wine, domestic or imported, added as a flavouring to that spirit as authorized under the Excise Act; (*substance aromatique*)
"**grain spirit**" means an alcoholic distillate, obtained from a mash of cereal grain or cereal grain products saccharified by the diastase of malt or by other enzymes and fermented by the action of yeast or a mixture of yeast and other micro-organisms, and from which all or nearly all of the naturally occurring substances other than alcohol and water have been removed; (*esprit de grain*)
23-3-93 "**malt spirit**" means an alcoholic distillate, obtained by pot-still distillation from a mash of cereal grain or cereal grain products saccharified by the diastase of malt and fermented by the action of yeast or a mixture of yeast and other micro-organisms; (*esprit de malt*)
"**molasses spirit**" means an alcoholic distillate, obtained from sugar-cane or sugar-cane products fermented by the action of yeast or a mixture of yeast and other micro-organisms, from which all or nearly all of the naturally occurring substances other than alcohol and water have been removed; (*esprit de mélasse*)
"**small wood**" means wood casks or barrels of not greater than 700 L capacity; (*petit fût*)
"**sweetening agent**" means glucose-fructose, fructose syrup or any food for which a standard is provided in Division 18, or any combination thereof. (*agent édulcorant*)

11-8-88 **B.02.003.** Where an alcoholic beverage contains 1.1 per cent or more alcohol by volume, the percentage by volume of alcohol present in the alcoholic beverage shall be shown on the principal display panel followed by the words "alcohol by volume" or the abbreviation "alc./vol.".

Whisky

15-12-93 †**B.02.010. [S].** **Whisky** or **Whiskey**, other than Malt Whisky, Scotch Whisky, Irish Whisky, Canadian Whisky, Canadian Rye Whisky, Rye Whisky, Highland Whisky, Bourbon Whisky and Tennessee Whisky,

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained from a mash of cereal grain or cereal grain products saccharified by the diastase of malt or by other enzymes and fermented by the action of yeast or a mixture of yeast and other micro-organisms; and
(b) may contain caramel and flavouring.

23-3-93 **B.02.011.** Revoked by P.C. 1993-535 of March 23, 1993.

B.02.012. Revoked by P.C. 1993-535 of March 23, 1993.

† **Note:** Section **B.02.010** shall come into force on the day on which section 10 of *An Act to implement the North American Free Trade Agreement*, being chapter 44 of the Statutes of Canada, 1993, comes into force.

B.02.013. [S]. Malt Whisky

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of a mash of malted grain fermented by the action of yeast or a mixture of yeast and other micro-organisms;
(b) shall possess the aroma, taste and character generally attributed to malt whisky; and
(c) may contain caramel and flavouring.

23-3-93

B.02.014. Revoked by P.C. 1993-535 of March 23, 1993.

B.02.015. Revoked by P.C. 1993-535 of March 23, 1993.

3-9-64

B.02.016. [S]. Scotch Whisky shall be whisky distilled in Scotland as Scotch whisky for domestic consumption in accordance with the laws of the United Kingdom.

B.02.017. No person shall blend or modify in any manner any Scotch whisky that is imported in bulk for the purpose of bottling and sale in Canada as Scotch whisky except by

(a) blending with other Scotch whisky;
(b) the addition of distilled or otherwise purified water to adjust to a required strength; or
(c) the addition of caramel.

3-9-64

B.02.018. [S]. Irish Whisky shall be whisky distilled in Northern Ireland or in the Republic of Ireland as Irish whisky for domestic consumption in accordance with the laws of Northern Ireland or the Republic of Ireland.

B.02.019. No person shall blend or modify in any manner any Irish whisky that is imported in bulk for the purpose of bottling and sale in Canada as Irish whisky except by

(a) blending with other Irish whisky;
(b) the addition of distilled or otherwise purified water to adjust to a required strength; or
(c) the addition of caramel.

B.02.020.[S]. (1) **Canadian Whisky, Canadian Rye Whisky** or **Rye Whisky**

(a) shall
  (i) be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained from a mash of cereal grain or cereal grain products saccharified by the diastase of malt or by other enzymes and fermented by the action of yeast or a mixture of yeast and other micro-organisms,
10-2-00 (ii) be aged in small wood for not less than three years,
  (iii) possess the aroma, taste and character generally attributed to Canadian whisky,
  (iv) be manufactured in accordance with the requirements of the *Excise Act* and the regulations made thereunder;
10-2-00 (v) be mashed, distilled and aged in Canada, and
  (vi) contain not less than 40 per cent alcohol by volume; and
23-3-93 (b) may contain caramel and flavouring.

(2) Subject to subsection (3), no person shall make any claim with respect to the age of Canadian whisky, other than for the period during which the whisky has been held in small wood.

(3) Where Canadian whisky has been aged in small wood for a period of at least three years, any period not exceeding six months during which that whisky was held in other containers may be claimed as age.

B.02.021. [S]. Highland Whisky

(a) shall be a potable alcoholic beverage blended in Canada from
23-3-93 (i) not less than 25 per cent malt whisky calculated on an absolute alcohol basis, distilled in Canada or Scotland, and
  (ii) whisky; and
(b) may, if it contains 51 per cent or more malt whisky distilled in Scotland, be labelled or advertised as containing malt whisky distilled in Scotland.

30-12-88

B.02.022. (1) Subject to subsection (2), no person shall label, package, sell or advertise any food as **Bourbon Whisky**, or in such a manner that it is likely to be mistaken for Bourbon whisky unless it is whisky manufactured in the United States as Bourbon whisky in accordance with the laws of the United States applicable in respect of Bourbon whisky for consumption in the United States.

(2) A person may modify Bourbon whisky that is imported for the purpose of bottling and sale in Canada as Bourbon whisky by the addition of distilled or otherwise purified water to adjust the Bourbon whisky to a required strength.

15-12-93

† **B.02.022.1.** (1) Subject to subsection (2), no person shall label, package, sell or advertise any food as **Tennessee Whisky**, or in such a manner that it is likely to be mistaken for Tennessee whisky unless it is a straight Bourbon whisky produced in the State of Tennessee and manufactured in the United States as Tennessee whisky in accordance with the laws of the United States applicable in respect of Tennessee whisky for consumption in the United States.

(2) A person may modify Tennessee whisky that is imported for the purpose of bottling and sale in Canada as Tennessee whisky by the addition of distilled or otherwise purified water to adjust the Tennessee whisky to a required strength.

15-12-93

† **B.02.023.** (1) Subject to sections B.02.022 and B.02.022.1, no person shall sell for consumption in Canada any whisky that has not been aged for a period of at least three years in small wood.

(2) Nothing in subsection (1) applies in respect of flavouring contained in whisky, but no person shall sell for consumption in Canada whisky containing any flavouring, other than wine, that has not been aged for a period of at least two years in small wood.

Rum

B.02.030. [S]. Rum

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained from sugar-cane or sugar-cane products fermented by the action of yeast or a mixture of yeast and other micro-organisms; and

(b) may contain

(i) caramel,

(ii) fruit and other botanical substances, and

(iii) flavouring and flavouring preparations.

23-3-93

B.02.031. (1) No person shall sell for consumption in Canada any rum that has not been aged for a period of at least one year in small wood.

(2) Nothing in subsection (1) applies in respect of flavouring contained in rum, but no person shall sell for consumption in Canada rum containing any flavouring, other than wine, that has not been aged for a period of at least one year in small wood.

B.02.032. Revoked by P.C. 1993-535 of March 23, 1993.

B.02.033. No person shall blend or modify in any manner any rum that is imported in bulk for the purpose of bottling and sale in Canada as imported rum except by

2-3-89

(a) blending with other imported rum;

(b) adding distilled or otherwise purified water to adjust the rum to the strength stated on the label applied to the container; or

(c) the addition of caramel.

† **Note**: Sections **B.02.022.1** and **B.02.023** shall come into force on the day on which section 10 of *An Act to implement the North American Free Trade Agreement*, being chapter 44 of the Statutes of Canada, 1993, comes into force.

B.02.034. (1) Notwithstanding section B.02.033, no person shall blend or modify in any manner any rum made from sugar cane products of a Commonwealth Caribbean country that has been distilled and fermented in a Commonwealth Caribbean country and imported in bulk from a Commonwealth Caribbean country for bottling and sale in Canada as Caribbean rum except by

(a) blending with other rum of a Commonwealth Caribbean country;
(b) blending with Canadian rum in proportions that result in 1 to 1.5 per cent Canadian rum by volume in the final product;
2-3-89 (c) adding distilled or otherwise purified water to adjust the rum to the strength stated on the label applied to the container; or
(d) adding caramel.

(2) In this section, "Commonwealth Caribbean country" means Anguilla, Antigua and Barbuda, Barbados, the Bahamas, Belize, Bermuda, the British Virgin Islands, the Caymen Islands, Dominica, Grenada, Guyana, Jamaica, Montserrat, St. Christopher and Nevis, Saint Lucia, St. Vincent and the Grenadines, Trinidad and Tobago and the Turks and Caicos Islands.

Gin

B.02.040. [S]. Hollands, Hollands Gin, Geneva, Geneva Gin, Genever, Genever Gin or **Dutch-type Gin**

(a) shall be a potable alcoholic beverage obtained
  (i) by the redistillation of malt spirit with or over juniper berries, or by a mixture of the products of more than one such redistillation,
  (ii) by the redistillation of a combination of malt spirit and not more than four times its volume on an absolute alcohol basis of grain spirit with or over juniper berries, or by a mixture of the products of more than one such redistillation, or
  (iii) by the blending of malt spirit, redistilled with or over juniper berries, with not more than four times its volume on an absolute alcohol basis of grain spirit or molasses spirit, or by a mixture of the products of more than one such blending;
(b) may contain
  (i) other aromatic botanical substances, added during the redistillation process, and
  (ii) caramel;
23-3-93 (c) shall not contain more than two per cent sweetening agent;
(d) may be labelled or advertised as being distilled, where subparagraph (a)(i) or (ii) is complied with; and
(e) shall be described on the principal display panel of its label and in any advertisements as blended gin, where subparagraph (a)(iii) is complied with.

B.02.041. [S]. Gin, other than Hollands, Hollands Gin, Geneva, Geneva Gin, Genever, Genever Gin or Dutch-type Gin,

(a) shall be a potable alcoholic beverage obtained
  (i) by the redistillation of alcohol from food sources with or over juniper berries, or by a mixture of the products of more than one such redistillation, or
  (ii) by the blending of alcohol from food sources, redistilled with or over juniper berries, with alcohol from food sources or by a mixture of the products of more than one such blending;
(b) may contain
  (i) other aromatic botanical substances, added during the redistillation process,
  (ii) a sweetening agent, and
  (iii) a flavouring preparation for the purpose of maintaining a uniform flavour profile; and
(c) may be labelled or advertised as Dry Gin or London Dry Gin if sweetening agents have not been added.

23-3-93 **B.02.042.** Revoked by P.C. 1993-535 of March 23, 1993.

B.02.043. No person shall make any claim for age for gin but gin that has been held in suitable containers may bear a label declaration to that effect.

Brandy

B.02.050. [S]. Brandy, other than Armagnac Brandy or Armagnac, Canadian Brandy, Cognac Brandy or Cognac, Dried Fruit Brandy, Fruit Brandy, Grappa, Lees Brandy and Pomace or Marc,

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of wine; and
(b) may contain
  (i) caramel,
  (ii) fruit and other botanical substances, and
  (iii) flavouring and flavouring preparations.

23-3-93

B.02.051. [S]. Armagnac Brandy or **Armagnac** shall be brandy manufactured in the Armagnac district of France in accordance with the laws of the French Republic for consumption in that country.

B.02.052. [S]. Canadian Brandy

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of wine that has been fermented in Canada; and
(b) may contain
  (i) caramel,
  (ii) fruit and other botanical substances, and
  (iii) flavouring and flavouring preparations.

B.02.053. [S]. Cognac Brandy or **Cognac** shall be brandy manufactured in the Cognac district of France in accordance with the laws of the French Republic for consumption in that country.

B.02.054. [S]. Dried Fruit Brandy

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained from sound dried fruit; and
(b) may contain
  (i) caramel,
  (ii) fruit and other botanical substances, and
  (iii) flavouring and flavouring preparations.

B.02.055. [S]. Fruit Brandy

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of
  (i) fruit wine or a mixture of fruit wines, or
  (ii) a fermented mash of sound ripe fruit other than grapes, or a mixture of sound ripe fruits other than grapes;
(b) may contain
  (i) caramel,
  (ii) fruit and other botanical substances, and
  (iii) flavouring and flavouring preparations; and
(c) may be described on its label as "(*naming the fruit*) brandy" if all of the fruit or fruit wine used to make the brandy originates from the named fruit.

B.02.056. [S]. Grappa

23-3-93

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of the pomace from sound ripe grapes after the removal of the juice or wine; and
(b) may contain
  (i) caramel
  (ii) fruit and other botanical substances, and
  (iii) flavouring and flavouring preparations.

B.02.057. [S]. Lees Brandy

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of the lees of wine or fruit wine;
(b) may contain
  (i) caramel,
  (ii) fruit and other botanical substances, and
  (iii) flavouring and flavouring preparations; and
(c) may be described on its label as "(*naming the fruit*) Lees Brandy" if all of the lees used to make the brandy originate from the named fruit.

B.02.058. [S]. Pomace or **Marc**

(a) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of the skin and pulp of sound ripe fruit after the removal of the fruit juice, wine or fruit wine;
(b) may contain
  (i) caramel,
  (ii) fruit and other botanical substances, and
  (iii) flavouring and flavouring preparations; and
(c) may be described on its label as "(*naming the fruit*) Pomace" or "(*naming the fruit*) Marc" if all of the skin and pulp used to make the brandy originate from the named fruit.

B.02.059. No person shall blend or modify in any manner any brandy that is imported in bulk for the purpose of bottling and sale in Canada as imported brandy, except by
(a) blending with other imported brandy;
(b) the addition of caramel; and
(c) the addition of distilled or otherwise purified water to adjust the brandy to a required strength.

B.02.060. Where brandy is wholly distilled in a country other than Canada, the label shall indicate the country of origin.

23-3-93

B.02.061. (1) No person shall sell any brandy that has not been aged for a period of at least one year in wooden containers or at least six months in small wood.

(2) Nothing in subsection (1) applies in respect of flavouring contained in brandy, but no person shall sell brandy containing any flavouring, other than wine, that has not been aged for a period of at least one year in wooden containers or at least six months in small wood.

(3) Nothing in subsection (1) or (2) applies in respect of brandy that meets the standards prescribed by any of sections B.02.051 to B.02.058.

(4) No person shall make any claim with respect to the age of brandy other than for the period during which the brandy has been held in wooden containers or in small wood.

Liqueurs and Spirituous Cordials

B.02.070. [S]. Liqueur or **Spirituous Cordial**

(a) shall be a product obtained by the mixing or distillation of alcohol from food sources with or over fruits, flowers, leaves or other botanical substances or their juices or with extracts derived by the infusion, percolation or maceration of those botanical substances;
(b) shall have added, during the course of manufacture, a sweetening agent in an amount that is not less than 2.5 per cent of the finished product;
(c) shall contain not less than 23 per cent absolute alcohol by volume; and
(d) may contain
  (i) natural and artificial flavouring preparations, and
  (ii) colour.

Vodka

B.02.080. [S]. Vodka shall be a potable alcoholic beverage obtained by the treatment of grain spirit or potato spirit with charcoal so as to render the product without distinctive character, aroma or taste.

Tequila

† **B.02.090.** (1) Subject to subsection (2), no person shall label, package, sell or advertise any food as **Tequila**, or in such a manner that it is likely to be mistaken for Tequila unless it is Tequila manufactured in Mexico as Tequila in accordance with the laws of Mexico applicable in respect of Tequila for consumption in Mexico.

(2) A person may modify Tequila that is imported for the purpose of bottling and sale in Canada as Tequila by the addition of distilled or otherwise purified water to adjust the Tequila to a required strength.

15-12-93

Mezcal

‡ **B.02.091.** (1) Subject to subsection (2), no person shall label, package, sell or advertise any food as **Mezcal**, or in such a manner that it is likely to be mistaken for Mezcal unless it is Mezcal manufactured in Mexico as Mezcal in accordance with the laws of Mexico applicable in respect of Mezcal for consumption in Mexico.

(2) A person may modify Mezcal that is imported for the purpose of bottling and sale in Canada as Mezcal by the addition of distilled or otherwise purified water to adjust the Mezcal to a required strength.

Wine

20-1-77 **B.02.100. [S]. Wine**

11-5-06 (a) shall be an alcoholic beverage that is produced by the complete or partial alcoholic fermentation of fresh grapes, grape must, products derived solely from fresh grapes, or any combination of them;

(b) may have added to it during the course of the manufacture

(i) yeast,

(ii) concentrated grape juice,

11-5-06 (iii) dextrose, fructose, glucose or glucose solids, invert sugar, sugar, or aqueous solutions of any of them,

(iv) yeast foods, in accordance with Table XIV to section B.16.100,

(v) calcium sulphate in such quantity that the content of soluble sulphates in the finished wine shall not exceed 0.2 per cent weight by volume calculated as potassium sulphate,

(vi) calcium carbonate in such quantity that the content of tartaric acid in the finished wine shall not be less than 0.15 per cent weight by volume,

(vii) sulphurous acid, including salts thereof, in such quantity that its content in the finished wine shall not exceed

(A) 70 parts per million in the free state, or

(B) 350 parts per million in the combined state, calculated as sulphur dioxide,

(viii) any of the following substances:

(A) citric acid, fumaric acid, lactic acid, malic acid, potassium bicarbonate, potassium carbonate, potassium citrate and tartaric acid, at a maximum level of use consistent with good manufacturing practice,

(B) metatartaric acid at a maximum level of use of 0.01 per cent, and

(C) potassium acid tartrate at a maximum level of use of 0.42 per cent,

(ix) amylase and pectinase at a maximum level of use consistent with good manufacturing practice,

11-5-06 (x) ascorbic acid or erythorbic acid, or their salts, at a maximum level of use consistent with good manufacturing practice,

(xi) antifoaming agents, in accordance with Table VIII to section B.16.100,

(xii) any of the following fining agents:

(A) activated carbon, albumen, casein, clay, diatomaceous earth, egg white, isinglass, polyvinylpolypyrrolidone and silicon dioxide,

(B) acacia gum, agar, gelatin and potassium ferrocyanide, at a maximum level of use consistent with good manufacturing practice,

(C) tannic acid at a maximum level of use of 200 parts per million, and

(D) polyvinylpyrrolidone in an amount that does not exceed 2 parts per million in the finished product,

(xiii) caramel at a maximum level of use consistent with good manufacturing practice,

18-9-75 (xiv) brandy, fruit spirit or alcohol derived from alcoholic fermentation of a food source distilled to not less than 94 per cent alcohol by volume,

† **Note**: Section **B.02.090** shall come into force on the day on which section 10 of *An Act to implement the North American Free Trade Agreement*, being chapter 44 of the Statutes of Canada, 1993, comes into force.

‡ **Note**: Section **B.02.091** shall come into force on the day on which section 10 of *An Act to implement the North American Free Trade Agreement*, being chapter 44 of the Statutes of Canada, 1993, comes into force or ninety days after the day on which the official standard for mezcal is made obligatory by the Government of Mexico, whichever is later.

11-5-06 (xv) any of the following substances:
(A) carbon dioxide and ozone at a maximum level of use consistent with good manufacturing practice, and
(B) oxygen,
(xvi) sorbic acid or salts thereof, not exceeding 500 parts per million calculated as sorbic acid,
11-5-06 (xvii) malolactic bacteria from the genera *Lactobacillus*, *Leuconostoc* and *Pediococcus*,
(xviii) copper sulphate in such a quantity that the content of copper in the finished product shall not exceed 0.0001 per cent,
(xix) nitrogen, and
(xx) oak chips and particles; and
(c) prior to final filtration may be treated with
31-1-66 (i) a strongly acid cation exchange resin in the sodium ion form or
(ii) a weakly basic anion exchange resin in the hydroxyl ion form

11-5-06 **B.02.101.** No person shall sell wine that contains more than 0.24 per cent weight by volume of volatile acidity calculated as acetic acid, as determined by official method FO-2, *Determination of Volatile Acidity of Wine, Cider and Champagne Cider*, October 15, 1981.

1-10-68 **B.02.102. [S].** **Fruit spirit** shall be an alcoholic distillate obtained from wine, fruit wine, grape pomace or fruit pomace.

3-9-64 **B.02.103. [S].** **Fruit Wine**, or (**naming the fruit**) **Wine** shall be the product of the alcoholic fermentation of the juice of sound ripe fruit other than grape, and in all other respects shall meet the requirements of the standard for wine as prescribed by section B.02.100.

3-9-64 **B.02.104. [S].** **Vermouth** shall be wine to which has been added bitters, aromatics or other botanical substances or a flavouring preparation, and shall contain not more than 20 per cent absolute alcohol by volume.

B.02.105. [S]. **Flavoured Wine, Wine Cocktail, Aperitif Wine** shall be wine to which has been added herbs, spices, other botanical substances, fruit juices or a flavouring preparation, and shall contain not more than 20 per cent absolute alcohol by volume.

28-4-77 **B.02.105A. [S].** **Flavoured (naming the fruit) Wine, (naming the fruit) Wine Cocktail**, or **Aperitif (naming the fruit) Wine** shall be fruit wine, a mixture of fruit wines, or a mixture of fruit wine and wine to which has been added herbs, spices, other botanical substances, fruit juices or a flavouring preparation, and shall contain not more than 20 per cent absolute alcohol by volume.

B.02.106. [S]. **Honey Wine**

30-4-96 (a) shall be the product of the alcoholic fermentation of an aqueous solution of honey; and
(b) may have added to it during the course of manufacture any of the following substances:
(i) yeast;
(ii) yeast foods;
(iii) sulphurous acid, including salts thereof, in such quantity that its content in the finished wine shall not exceed
10-2-72 (A) 70 ppm in the free state, or
(B) 350 ppm in the combined state, calculated as sulphur dioxide;
(iv) tartaric or citric acid;
(v) potassium acid tartrate;
(vi) natural botanical flavours;
18-9-75 (vii) fruit spirit or alcohol derived from the alcoholic fermentation of a food source distilled to not less than 94 per cent alcohol by volume;
(viii) caramel;
(ix) carbon dioxide;
(x) activated carbon, clay or tannic acid as fining agents; or
30-4-96 (xi) sorbic acid, and any salts thereof, calculated as sorbic acid, in a quantity such that the content of sorbic acid and its salts in the finished wine does not exceed 500 parts per million.

3-9-64 **B.02.107. [S].** **May Wine** shall be wine to which has been added artificial woodruff flavouring preparation.

12-4-84 **B.02.108.** A clear indication of the country of origin shall be shown on the principal display panel of a wine.

Cider

B.02.120. [S]. Cider

(a) shall
12-4-84 (i) be the product of the alcoholic fermentation of apple juice, and
(ii) contain not less than 2.5 per cent and not more than 13.0 per cent absolute alcohol by volume; and

(b) may have added to it during the course of manufacture
(i) yeast,
(ii) concentrated apple juice,
(iii) sugar, dextrose, invert sugar, glucose, glucose solids, or aqueous solutions thereof,
(iv) yeast foods,
(v) sulphurous acid, including salts thereof, in such quantity that its content in the finished cider shall not exceed
(A) 70 parts per million in the free state, or
(B) 350 parts per million in the combined state, calculated as sulphur dioxide,
(vi) tartaric acid and potassium tartrate,
(vii) citric acid,
(viii) lactic acid,
(ix) pectinase and amylase,
25-8-76 (x) ascorbic or erythorbic acid, or salts thereof,
(xi) any of the following fining agents:
(A) activated carbon,
(B) clay,
(C) diatomaceous earth,
(D) gelatin,
(E) albumen,
(F) sodium chloride,
(G) silica gel,
(H) casein,
12-4-84 (I) tannic acid not exceeding 200 parts per million, or
(J) polyvinylpyrolidone not exceeding 2 parts per million in the finished product,
(xii) caramel,
(xiii) brandy fruit spirit or alcohol derived from the alcoholic fermentation of a food source distilled to not less than 94 per cent alcohol by volume,
(xiv) carbon dioxide,
(xv) oxygen,
12-4-84 (xvi) ozone, or
9-7-81 (xvii) sorbic acid or salts thereof, not exceeding 500 parts per million, calculated as sorbic acid.

B.02.122. [S]. **Champagne Cider** shall be cider that is impregnated with carbon dioxide under pressure by

3-9-64 (a) conducting the afterpart of the fermentation in closed vessels; or
12-4-84 (b) secondary fermentation in closed vessels with or without the addition of sugar, dextrose, invert sugar, glucose or glucose solids or aqueous solutions thereof,
25-8-76 and shall contain not less than 7 per cent absolute alcohol by volume.

5-8-82 **B.02.123.** No person shall sell cider or champagne cider that has more than 0.2 per cent weight by volume of volatile acidity calculated as acetic acid, as determined by official method FO-2, Determination of Volatile Acidity of Wine, Cider and Champagne Cider, October 15, 1981.

Beer

B.02.130. [S]. Beer

(a) shall be the product of the alcoholic fermentation by yeast of an infusion of barley or wheat malt and hops or hop extract in potable water and shall be brewed in such a manner as to possess the aroma, taste and character commonly attributed to beer; and

(b) may have added to it during the course of manufacture any of the following ingredients:

(i) cereal grain,
(ii) carbohydrate matter,
(iii) salt,
(iv) hop oil,
(v) hop extract, if the hop extract is added to the wort before or during cooking,
(vi) pre-isomerized hop extract,
5-11-96 (vi.1) reduced isomerized hop extract,
(vii) Irish moss seaweed of the species Chondrus crispus,
(viii) carbon dioxide,
(ix) caramel,
11-8-88 (x) dextrin,
(xi) food enzymes,
(xii) stabilizing agents,
(xiii) pH adjusting and water correcting agents,
(xiv) Class I preservatives,
(xv) Class II preservatives,
(xvi) sequestering agent,
(xvii) yeast foods,
11-5-06 (xviii) any of the following fining agents: acacia gum, activated carbon, aluminum silicate, bentonite, calcium silicate, cellulose, China clay, diatomaceous earth, gelatin, isinglass, magnesium silicate, Nylon 66, polyvinylpolypyrrolidone, silica gel and wood shavings derived from beech, cherry, hazelnut and oak wood,
(xix) polyvinylpyrrolidone,
(xx) ammonium persulphate,
(xxi) in the case of wort, dimethylpolysiloxane, and
(xxii) in the case of mash, hydrogen peroxide.

B.02.131. [S]. Ale, Stout, Porter or **Malt Liquor**

(a) shall be the product of the alcoholic fermentation by yeast of an infusion of barley or wheat malt and hops or hop extract in potable water and shall be brewed in such a manner as to possess the aroma, taste and character commonly attributed to ale, stout, porter, or malt liquor, respectively; and
(b) may have added to it during the course of manufacture any of the ingredients referred to in paragraph B.02.130(b).

B.02.132. Where a beer, ale, stout, porter or malt liquor contains the percentage of alcohol by volume set out in column I of an item of the table, the qualified common name or common name set out in column II of that item shall be used in any advertisement of and on the label of the beer, ale, stout, porter or malt liquor.

TABLE

Item	*Column I* *Percentage alcohol by volume*	*Column II* *Qualified common name or Common name*
1.	1.1 to 2.5	Extra Light Beer, Extra Light Ale, Extra Light Stout, Extra Light Porter
2.	2.6 to 4.0	Light Beer, Light Ale, Light Stout, Light Porter
3.	4.1 to 5.5	Beer, Ale, Stout, Porter
4.	5.6 to 8.5	Strong Beer, Strong Ale, Strong Stout, Strong Porter, Malt Liquor
5.	8.6 or more	Extra Strong Beer, Extra Strong Ale, Extra Strong Stout, Extra Strong Porter, Strong Malt Liquor

11-8-88

B.02.133. [S]. In this Division, "hop extract" means an extract derived from hops by a process employing the solvent

(a) hexane, methanol, or methylene chloride in such a manner that the hop extract does not contain more than 2.2 per cent of the solvent used; or
(b) carbon dioxide or ethyl alcohol in an amount consistent with good manufacturing practice.

B.02.134. [S]. (1) In this Division, "pre-isomerized hop extract" means an extract derived from hops by

(a) the use of one of the following solvents:
  (i) hexane,
  (ii) carbon dioxide, or
  (iii) ethanol; and
(b) the subsequent isolation of the alpha acids and their conversion to isomerized alpha acids by means of diluted alkali and heat.

(2) For the purposes of paragraph (1)(b), the residues of hexane shall not exceed 1.5 parts per million per per cent iso-alpha acid content of the pre-isomerized hop extract.

B.02.135. [S]. In this Division, "reduced isomerized hop extract" means

(a) tetrahydroisohumulones derived from hops
  (i) by isomerization and reduction of humulones (alpha-acids) by means of hydrogen and a catalyst, or
  (ii) by reduction of lupulones (beta-acids) by means of hydrogen and a catalyst, followed by oxidation and isomerization;
(b) hexahydroisohumulones derived from hops by reduction of tetrahydroisohumulones by means of sodium borohydride; and
(c) dihydroisohumulones derived from hops by reduction of isoalpha acids by means of sodium borohydride.

5-11-96

13-9-00

*(R) Minor correction

Baking Powder

3-9-64 **B.03.001.** In this Division, "acid-reacting material" means one or any combination of

(a) lactic acid or its salts;
(b) tartaric acid or its salts;
(c) acid salts of phosphoric acid; and
(d) acid compounds of aluminum.

29-10-92 **B.03.002. [S]. Baking Powder** shall be a combination of sodium or potassium bicarbonate, an acid-reacting material, starch or other neutral material, may contain an anticaking agent and shall yield not less than 10 per cent of its weight of carbon dioxide, as determined by official method FO-3, Determination of Carbon Dioxide in Baking Powder, October 15, 1981.

*(R) Minor correction

Cocoa and Chocolate Products

B.04.001. The definitions in this section apply in this Division.

"**chocolate product**" means a product derived from one or more cocoa products and includes chocolate, bittersweet chocolate, semi-sweet chocolate, dark chocolate, sweet chocolate, milk chocolate and white chocolate. (*produit de chocolat*)

"**cocoa product**" means a product derived from cocoa beans and includes cocoa nibs, cocoa liquor, cocoa mass, unsweetened chocolate, bitter chocolate, chocolate liquor, cocoa, low fat cocoa, cocoa powder and low fat cocoa powder. (*produit du cacao*)

"**milk ingredient**" means one or any combination of

(a) the following products for which a standard is prescribed in this Part, namely,
  (i) milk or whole milk,
  (ii) skim milk,
  (iii) partly skimmed milk or partially skimmed milk,
  (iv) sterilized milk,
  (v) condensed milk or sweetened condensed milk,
  (vi) evaporated milk,
  (vii) evaporated skim milk or concentrated skim milk,
  (viii) evaporated partly skimmed milk or concentrated partly skimmed milk,
  (ix) milk powder or whole milk powder or dry whole milk or powdered whole milk,
  (x) skim milk powder or dry skim milk,
  (xi) skim milk with added milk solids,
  (xii) partly skimmed milk with added milk solids or partially skimmed milk with added milk solids,
  (xiii) malted milk or malted milk powder,
  (xiv) butter, and
  (xv) cream; and

(b) the following products for which a standard is not prescribed by this Part, namely
  (i) reconstituted milk or whole milk,
20-5-97 (ii) reconstituted skim milk,
  (iii) reconstituted partly skimmed milk,
  (iv) partly skimmed milk powder,
  (v) buttermilk,
  (vi) butter oil, and
  (vii) reconstituted cream.

(*ingrédient laitier*)

"**sweetening ingredient**" means any one or any combination of sweetening agents, except for icing sugar. (*ingrédient édulcorant*)

B.04.002. [S]. **Cocoa Beans** shall be the seeds of *Theobroma cacao L.* or a closely related species.

B.04.003. [S]. **Cocoa Nibs** shall be the product prepared by removing the shell from cleaned cocoa beans, of which the residual shell content may not exceed 1.75 per cent by mass, calculated to an alkali free basis if the nibs or the cocoa beans from which the nibs were prepared have been processed with alkali, as determined by the method prescribed in the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 12th Ed. (1975), sections 13.010 to 13.014, under the heading "Shell in Cacao Nibs - Official Final Action", published by the Association of Official Analytical Chemists, in Washington.

B.04.004. [S]. **Cocoa Liquor, Cocoa Mass, Unsweetened Chocolate, Bitter Chocolate** or **Chocolate Liquor** shall

(a) be the product obtained from the mechanical disintegration of the cocoa nib with or without removal or addition of any of its constituents; and
(b) contain not less than 50 per cent cocoa butter.

B.04.005. (1) Cocoa products may be processed with one or more of the following pH-adjusting or alkalizing agents:

(a) hydroxides of ammonia, carbonates of ammonia, bicarbonates of ammonia, hydroxides of sodium, carbonates of sodium, bicarbonates of sodium, hydroxides of potassium, carbonates of potassium or bicarbonates of potassium;
(b) carbonates of magnesium or hydroxides of magnesium; and
(c) carbonates of calcium.

(2) The quantity of any one pH-adjusting agent referred to in paragraphs (1)(a) to (c) shall not exceed the maximum level of use for that agent set out in column III of an item of Table X to section B.16.100.

(3) The total mass of the pH-adjusting agents referred to in paragraphs (1)(a) to (c) shall not be greater in neutralizing value, calculated from the respective masses of those agents, than the neutralizing value of five parts by mass of anhydrous potassium carbonate for each 100 parts by mass of cocoa product, calculated on a fat-free basis.

(4) Cocoa products may be processed with one or more of the following pH-adjusting or neutralizing agents, added as such or in aqueous solution:

(a) phosphoric acid;
(b) citric acid; and
(c) L-tartaric acid.

(5) The total mass of pH-adjusting agents referred to in subsection (4) shall not exceed in neutralizing value, calculated from the respective masses of those agents, the appropriate maximum levels of use set out in column III of Table X to section B.16.100.

(6) For the purpose of subsection (5),
(a) the total quantity of phosphoric acid shall not be greater than 0.5 part by mass, expressed as P_2O_5, for each 100 parts by mass of cocoa product, calculated on a fat-free basis; and
(b) the total quantity, singly or in combination, of citric acid and L-tartaric acid shall not be greater than 1.0 part by mass for each 100 parts by mass of cocoa product, calculated on a fat-free basis.

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B.04.006. [S]. Chocolate, Bittersweet Chocolate, Semi-sweet Chocolate or **Dark Chocolate**

(a) shall be one or more of the following combined with a sweetening ingredient, namely,
  (i) cocoa liquor,
  (ii) cocoa liquor and cocoa butter, and
  (iii) cocoa butter and cocoa powder;
(b) shall contain not less than 35 per cent total cocoa solids, of which
  (i) not less than 18 per cent is cocoa butter, and
  (ii) not less than 14 per cent is fat-free cocoa solids; and
(c) may contain
  (i) less than 5 per cent total milk solids from milk ingredients,
  (ii) spices,
  (iii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,
  (iv) salt, and
  (v) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of chocolate product, namely,
    (A) mono-glycerides and mono- and diglycerides,
    (B) lecithin and hydroxylated lecithin,
    (C) ammonium salts of phosphorylated glycerides,
    (D) polyglycerol esters of interesterified castor oil fatty acids, and
    (E) sorbitan monostearate.

*(R) Minor correction

B.04.007. [S]. Sweet Chocolate

(a) shall be one or more of the following combined with a sweetening ingredient, namely,
  (i) cocoa liquor,
  (ii) cocoa liquor and cocoa butter, and
  (iii) cocoa butter and cocoa powder;
(b) shall contain not less than 30 per cent total cocoa solids, of which
  (i) 18 per cent is cocoa butter, and
  (ii) 12 per cent is fat-free cocoa solids; and
(c) may contain
  (i) less than 12 per cent total milk solids from milk ingredients,
  (ii) spices,
  (iii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,
  (iv) salt, and
  (v) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of chocolate product, namely,
    (A) mono-glycerides and mono- and diglycerides,
    (B) lecithin and hydroxylated lecithin,
    (C) ammonium salts of phosphorylated glycerides,
    (D) polyglycerol esters of interesterified castor oil fatty acids, and
    (E) sorbitan monostearate.

B.04.008. [S]. Milk Chocolate

(a) shall be one or more of the following combined with a sweetening ingredient, namely,
  (i) cocoa liquor,
  (ii) cocoa liquor and cocoa butter, and
  (iii) cocoa butter and cocoa powder;

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(b) shall contain not less than
  (i) 25 per cent total cocoa solids, of which
    (A) not less than 15 per cent is cocoa butter, and
    (B) not less than 2.5 per cent is fat-free cocoa solids,
  (ii) 12 per cent total milk solids from milk ingredients, and
  (iii) 3.39 per cent milk fat; and
(c) may contain
  (i) less than 5 per cent whey or whey products,
  (ii) spices,
  (iii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,
  (iv) salt, and
  (v) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of chocolate product, namely,
    (A) mono-glycerides and mono- and diglycerides,
    (B) lecithin and hydroxylated lecithin,
    (C) ammonium salts of phosphorylated glycerides,
    (D) polyglycerol esters of interesterified castor oil fatty acids, and
    (E) sorbitan monostearate.

B.04.009. [S]. White Chocolate

(a) shall contain the following combined together, namely,
  (i) not less than 20 per cent cocoa butter,
  (ii) not less than 14 per cent total milk solids from milk ingredients, and
  (iii) not less than 3.5 per cent milk fat; and
(b) may contain
  (i) less than 5 per cent whey or whey products,
  (ii) spices,

(iii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,
(iv) salt, and
(v) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of chocolate product, namely,
(A) mono-glycerides and mono- and diglycerides,
(B) lecithin and hydroxylated lecithin,
(C) ammonium salts of phosphorylated glycerides,
(D) polyglycerol esters of interesterified castor oil fatty acids, and
(E) sorbitan monostearate.

B.04.010. [S]. Cocoa or **Cocoa Powder**

(a) shall be the product that
(i) is obtained by pulverising the remaining material from partially defatted cocoa liquor by mechanical means, and
(ii) contains not less than 10 per cent cocoa butter; and
(b) may contain
(i) spices,
(ii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,
(iii) salt, and
(iv) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of cocoa product, namely,
(A) mono-glycerides and mono- and diglycerides,
(B) lecithin and hydroxylated lecithin, and
(C) ammonium salts of phosphorylated glycerides.

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B.04.011. [S]. Low Fat Cocoa or **Low Fat Cocoa Powder**

(a) shall be the product that:
(i) is obtained by pulverising the remaining material from partially defatted cocoa liquor by mechanical means, and
(ii) contains less than 10 per cent cocoa butter; and
(b) may contain
(i) spices,
(ii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,
(iii) salt, and
(iv) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of cocoa product, namely,
(A) mono-glycerides and mono- and diglycerides,
(B) lecithin and hydroxylated lecithin, and
(C) ammonium salts of phosphorylated glycerides.

B.04.012. No person shall sell a cocoa product or a chocolate product unless it is free from bacteria of the genus *Salmonella* as determined by official method MFO-11, *Microbiological Examination of Cocoa and Chocolate*, November 30, 1981.

Coffee

3-9-64 **B.05.001. [S]. Green Coffee, Raw Coffee** or **Unroasted Coffee** shall be the seed of *Coffee arabica L., C. liberica* Hiern, or *C. robusta* Chev., freed from all but a small portion of its spermoderm.

3-9-64 **B.05.002. [S].** Roasted Coffee or **Coffee** shall be roasted green coffee, and shall contain not less than 10 per cent fat, and may contain not more than 6 per cent total ash.

B.05.003. [S]. Decaffeinated (indicating the type of coffee).

(a) shall be coffee of the type indicated, from which caffeine has been removed and that, as a result of the removal, contains not more than

27-7-90 (i) 0.1 per cent caffeine, in the case of decaffeinated raw coffee and decaffeinated coffee, or

(ii) 0.3 per cent caffeine, in the case of decaffeinated instant coffee; and

(b) may have been decaffeinated by means of extraction solvents set out in Table XV to Division 16.

*(R) Minor correction

Food Colours

B.06.001. In this Division,

"**diluent**" means any substance other than a synthetic colour present in a colour mixture or preparation; (*diluant*)
"**dye**" means the principal dye and associated subsidiary and isomeric dyes contained in a synthetic colour; (*pigment*)
"**mixture**" means a mixture of two or more synthetic colours or a mixture of one or more synthetic colours with one or more diluents; (*mélange*)
"**official method FO-7**" means official method FO-7, Determination of Dye Content of Synthetic Food Colours, March 15, 1984; (*méthode officielle FO-7*)
"**official method FO-8**" means official method FO-8, Determination of Water Insoluble Matter in Synthetic Food Colours, March 15, 1984; (*méthode officielle FO-8*)
"**official method FO-9**" means official method FO-9, Determination of Combined Ether Extracts in Synthetic Food Colours, March 15, 1984; (*méthode officielle FO-9*)
"**official method FO-10**" means official method FO-10, Determination of Subsidiary Dyes in Synthetic Food Colours, March 15, 1984; (*méthode officielle FO-10*)
7-6-84 "**official method FO-11**" means official method FO-11, Determination of Intermediates in Synthetic Food Colours, March 15, 1984; (*méthode officielle FO-11*)
"**official method FO-12**" means official method FO-12, Determination of Volatile Matter in Citrus Red No. 2, March 15, 1984; (*méthode officielle FO-12*)
"**official method FO-13**" means official method FO-13, Determination of Sulphated Ash in Citrus Red No. 2, March 15, 1984; (*méthode officielle FO-13*)
"**official method FO-14**" means official method FO-14, Determination of Water Soluble Matter in Citrus Red No. 2, March 15, 1984; (*méthode officielle FO-14*)
"**official method FO-15**" means official method FO-15, Determination of Carbon Tetrachloride Insoluble Matter in Citrus Red No. 2, March 15, 1984; (*méthode officielle FO-15*)
"**preparation**" means a preparation of one or more synthetic colours containing less than three per cent dye and sold for household use; (*préparation*)
"**synthetic colour**" means any organic colour, other than caramel, that is produced by chemical synthesis and has no counterpart in nature and for which a standard is prescribed in Section B.06.041 to B.06.053. (*colorant synthétique*)

B.06.002. No person shall sell a food, other than a synthetic colour, mixture, preparation or flavouring preparation, that contains, when prepared for consumption according to label directions, more than

7-6-84
(a) 300 parts per million of Allura Red, Amaranth, Erythrosine, Tartrazine, Sunset Yellow FCF or Indigotine or any combination of these colours;
(b) 100 parts per million of Fast Green FCF or Brilliant Blue FCF or any combination of those colours;
(c) 300 parts per million of any combination of the synthetic colours named in paragraphs (a) and (b) within the limits set by those paragraphs; or
26-6-80 (d) 150 parts per million of Ponceau SX.

B.06.003. No person shall sell a colour for use in or upon food that contains more than

(a) three parts per million of arsenic, calculated as arsenic, as determined by official method FO-4, Determination of Arsenic in Food Colours, October 15, 1981;
5-8-82 (b) 10 parts per million of lead, calculated as lead, as determined by official method FO-5, Determination of Lead in Food Colours, October 15, 1981; or
(c) 40 parts per million of heavy metals, except in the case of iron oxide, titanium dioxide, aluminum metal and silver metal.

26-6-80 **B.06.004.** No person shall sell a synthetic colour for use in or upon food unless

(a) the label carries the lot number and common name of the synthetic colour and the words "Food Colour";
(b) the Director, or an agency acceptable to the Director, has certified that each lot meets the requirements of section B.06.003 and the standard for such colour as prescribed in sections B.06.041 to B.06.053; and
(c) where the synthetic colour is certified by an agency, a copy of the certificate has been submitted to and accepted by the Director.

B.06.005. No person shall import a synthetic colour for use in or upon food unless

(a) the Director, or an agency acceptable to the Director, has certified that each lot meets the requirements of section B.06.003 and the standard for such colour as prescribed in sections B.06.041 to B.06.053; and
(b) where the synthetic colour is certified by an agency, a copy of the certificate has been submitted to and accepted by the Director.

B.06.006. No person shall sell a mixture for use in or upon food unless the label carries the lot number of the mixture and the words "Food Colour".

B.06.007. No person shall sell a preparation for use in or upon food unless

26-6-80 (a) the label carries the words "Food Colour Preparation" on its principal display panel; and
(b) in the case of a liquid preparation, the container has a capacity of 60 ml or less and will permit dropwise discharge only.

B.06.008. No person shall import or sell a mixture or preparation for use in or upon food unless

(a) the Director, or an agency acceptable to the Director, has certified that any synthetic colour contained therein meets the requirements of section B.06.003 and the standard for such colour as prescribed in sections B.06.041 to B.06.053; or
(b) any synthetic colour contained therein has been previously certified and the certificate has been accepted as required by sections B.06.004 and B.06.005.

Natural Colours

B.06.021. [S]. Oil-soluble Annatto, Annatto Butter Colour, or **Annatto Margarine Colour**

(a) shall be the extractives of Bixa orellana seeds
23-1-75 (i) dissolved in vegetable oil, castor oil, monoglycerides and diglycerides, propylene glycol or propylene glycol monoesters and diesters of fat-forming fatty acids, with or without 1.0 per cent potassium hydroxide, or
3-9-64 (ii) suspended upon sugar, lactose, starch or hydrated calcium silicate, with or without calcium phosphate, potassium aluminum sulphate, sodium bicarbonate or salt; and
(b) shall contain not less than 0.30 per cent total pigments calculated as natural (*cis*-) bixin, which pigments shall consist of not less than 40 per cent natural (*cis*-) bixin.

25-3-65 **B.06.022. [S].** **β-Carotene** shall be the food colour chemically known as β-carotene that is manufactured synthetically and shall conform to the following specifications:

(a) 1 per cent solution in chloroform ..... clear;
(b) loss of weight on drying ..... not more than 0.2 per cent;
25-3-65 (c) residue on ignition ..... not more than 0.2 per cent; and
(d) assay (spectrophotometric) ..... 96 to 101 per cent.

B.06.023. [S]. **β-Apo-8'-Carotenal** shall be the food colour chemically known as β-apo-8'-carotenal and shall conform to the following specifications:

25-3-65

(a) 1 per cent solution in chloroform ..... clear;
(b) melting point (decompositition) ..... 136°C to 140°C (corrected);
(c) loss of weight on drying ..... not more than 0.2 per cent;
(d) residue on ignition ..... not more than 0.2 per cent; and
(e) assay (spectrophotometric) ..... 96 to 101 per cent.

B.06.024. [S]. **Canthaxanthin** shall be the food colour chemically known as canthaxanthin and shall conform to the following specifications:

15-5-68

(a) 1 per cent solution in chloroform ..... clear;
(b) loss of weight on drying ..... not more than 0.2 per cent; and
(c) assay (spectrophotometric) ..... 96 to 101 per cent.

B.06.025. [S]. **Ethyl β-apo-8'-carotenoate** shall be the food colour chemically known as ethyl β-apo-8'-carotenoate and shall conform to the following specifications:

10-3-70

(a) 1 per cent solution in chloroform ..... clear;
(b) loss of weight on drying ..... not more than 0.2 per cent; and
(c) assay (spectrophotometric) ..... 96 to 101 per cent.

Inorganic Colours

B.06.031. [S]. Carbon black shall be carbon prepared from natural gas by the "channel" or "impingement" process and shall contain no higher aromatic hydrocarbons or tarry materials as determined by official method FO-6, *Determination of Higher Aromatic Hydrocarbons or Tarry Materials in Carbon Black and Charcoal*, October 15, 1981.

5-8-82

B.06.032. [S]. Charcoal shall be carbon prepared by the incomplete combustion of vegetable matter and shall contain no higher aromatic hydrocarbons or tarry materials as determined by official method FO-6, *Determination of Higher Aromatic Hydrocarbons or Tarry Materials in Carbon Black and Charcoal*, October 15, 1981.

10-3-70

B.06.033. [S]. **Titanium Dioxide** shall be the chemical substance known as titanium dioxide and shall contain not less than 99 per cent titanium dioxide, and notwithstanding section B.06.006, shall contain not more than 50 parts per million of total antimony expressed as the metal and as determined by an acceptable method.

Synthetic Colours

B.06.041. [S]. **Amaranth** shall be the trisodium salt of 1-(4-sulpho-1-naphthylazo)-2-naphthol-3,6-disulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

7-6-84

(a) 0.2 per cent water insoluble matter, as determined by official method FO-8;
(b) 0.2 per cent combined ether extracts, as determined by official method FO-9;
(c) 4.0 per cent subsidiary dyes, as determined by official method FO-10; and
(d) 0.5 per cent intermediates, as determined by official method FO-11.

*(R) Minor correction

83, June 7, 1984
Replaces page 33, August 5, 1982

B.06.042. [S]. Erythrosine shall be the disodium salt of 2,4,5,7-tetraiodofluorescein, shall contain not less than 85 per cent dye calculated as the monohydrate, as determined by official method FO-7, and may contain not more than

(a) 0.2 per cent water insoluble matter, as determined by official method FO-8;
(b) 0.2 per cent combined ether extracts, as determined by official method FO-9;
(c) 5.0 per cent subsidiary dyes, as determined by official method FO-10; and
(d) 0.5 per cent intermediates, as determined by official method FO-11.

B.06.043. [S]. Ponceau SX shall be the disodium salt of 2-(5-sulpho-2,4-xylylazo)-1-naphthol-4-sulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(a) 0.2 per cent water insoluble matter, as determined by official method FO-8;
(b) 0.2 per cent combined ether extracts, as determined by official method FO-9;
(c) 1.0 per cent subsidiary dyes, as determined by official method FO-10; and
(d) 0.5 per cent intermediates, as determined by official method FO-11.

7-6-84

B.06.044. [S]. Allura Red shall be the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulphophenyl)azo]-2-naphthalene sulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(a) 0.2 per cent water insoluble matter, as determined by official method FO-8;
(b) 0.2 per cent combined ether extracts, as determined by official method FO-9;
(c) 4.0 per cent subsidiary dyes, as determined by official method FO-10; and
(d) 0.5 per cent intermediates, as determined by official method FO-11.

B.06.045. [S]. Tartrazine shall be the trisodium salt of 3-carboxy-5-hydroxy-1-***p***-sulphophenyl-4-***p***-sulpho-phenylazopyrazole, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(a) 0.2 per cent water insoluble matter, as determined by official method FO-8;
(b) 0.2 per cent combined ether extracts, as determined by official method FO-9;
(c) 1.0 per cent subsidiary dyes, as determined by official method FO-10; and
(d) 0.5 per cent intermediates, as determined by official method FO-11.

B.06.046. [S]. Sunset Yellow FCF shall be the disodium salt of 1-***p***-sulphophenylazo-2-naphthol-6-sulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(a) 0.2 per cent water insoluble matter, as determined by official method FO-8;
(b) 0.2 per cent combined ether extracts, as determined by official method FO-9;
(c) 5.0 per cent subsidiary dyes, as determined by official method FO-10; and
(d) 0.5 per cent intermediates, as determined by official method FO-11.

B.06.049. [S]. Fast Green FCF shall be the disodium salt of 4,4'-di(***N***-ethyl-***m***-sulphobenzylamino)-2''-sulpho-4''-hydroxytriphenylmethanol anhydride, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(a) 0.2 per cent water insoluble matter, as determined by official method FO-8;
(b) 0.4 per cent combined ether extracts, as determined by official method FO-9;
(c) 5.0 per cent subsidiary dyes, as determined by official method FO-10; and
(d) 1.0 per cent intermediates, as determined by official method FO-11.

B.06.050. [S]. Indigotine shall be the disodium salt of indigotine-5,5'-disulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(a) 0.2 per cent water insoluble matter, as determined by official method FO-8;
(b) 0.4 per cent combined ether extracts, as determined by official method FO-9;
(c) 1.0 per cent subsidiary dyes, as determined by official method FO-10; and
(d) 0.5 per cent intermediates, as determined by official method FO-11.

B.06.051. [S]. Brilliant Blue FCF shall be the disodium salt of 4,4'-di(***N***-ethyl-***m***-sulphobenzyl-amino)-2"-sulphotriphenylmethanol anhydride, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(a) 0.2 per cent water insoluble matter, as determined by official method FO-8;
7-6-84 (b) 0.4 per cent combined ether extracts, as determined by official method FO-9;
(c) 5.0 per cent subsidiary dyes, as determined by official method FO-10; and
(d) 2.0 per cent intermediates, as determined by official method FO-11.

B.06.053. [S]. Citrus Red No. 2 shall be 1-(2,5-dimethoxyphenylazo)-2-naphthol, shall contain not less than 98 per cent dye, as determined by official method FO-7, and may contain not more than

(a) 0.5 per cent volatile matter (at 100°C), as determined by official method FO-12;
(b) 0.3 per cent sulphated ash, as determined by official method FO-13;
(c) 0.3 per cent water soluble matter, as determined by official method FO-14;
(d) 0.5 per cent carbon tetrachloride insoluble matter, as determined by official method FO-15;
(e) 0.05 per cent uncombined intermediates; and
(f) 2.0 per cent subsidiary dyes.

6-11-87 **B.06.061.** The lake of any water soluble synthetic colour for which a standard is provided in sections B.06.041, B.06.042, B.06.043, B.06.044, B.06.045, B.06.046, B.06.049, B.06.050 or B.06.051 shall be the calcium or aluminum salt of the respective colour extended on alumina.

5-8-82 **B.06.062.** Revoked by P.C. 1982-2378 of August 5, 1982.

Spices, Dressing and Seasonings

B.07.001. [S]. Allspice or **Pimento**, whole or ground, shall be the dried, full but unripe whole berries of *Pimenta dioica (L) Merr.* and shall contain

(a) not more than
  (i) 25 per cent crude fibre,
  (ii) 5.5 per cent total ash,
  (iii) 0.4 per cent ash insoluble in hydrochloric acid, and
  (iv) 12 per cent moisture; and
(b) not less than 2.5 millilitres volatile oil per 100 grams of spice.

B.07.002. [S]. Anise or **Anise Seed**, whole or ground, shall be the dried fruit of *Pimpinella anisum L.* and shall contain

(a) not more than
  (i) 9 per cent total ash,
  (ii) 1 per cent ash insoluble in hydrochloric acid, and
  (iii) 10 per cent moisture; and
(b) not less than 2 millilitres volatile oil per 100 grams of spice.

B.07.003. [S]. Basil or **Sweet Basil**, whole or ground, shall be the dried leaves of *Ocimum basilicum L.* and shall contain

(a) not more than
  (i) 15 per cent total ash,
  (ii) 2 per cent ash insoluble in hydrochloric acid, and
  (iii) 9 per cent moisture; and
13-9-79 (b) not less than 0.2 millilitre volatile oil per 100 grams of spice.

B.07.004. [S]. Bay leaves or **Laurel Leaves**, whole or ground, shall be the dried leaves of *Laurus nobilis L.* and shall contain

(a) not more than
  (i) 4.5 per cent total ash,
  (ii) 0.5 per cent ash insoluble in hydrochloric acid, and
  (iii) 7 per cent moisture; and
(b) not less than 1 millilitre volatile oil per 100 grams of spice.

B.07.005. [S]. Caraway or **Caraway Seed**, whole or ground, shall be the dried fruit of the caraway plant, *Carum carvi L.* and shall contain

(a) not more than
  (i) 8 per cent total ash,
  (ii) 1 per cent ash insoluble in hydrochloric acid, and
  (iii) 11.5 per cent moisture; and
(b) not less than 2 millilitres volatile oil per 100 grams of spice.

B.07.006. [S]. Cardamom or **Cardamom Seed**, bleached or green, whole or ground, shall be the dried ripe fruit of *Elettaria cardamomum Maton* and shall contain

(a) not more than
  (i) 8 per cent total ash,
  (ii) 3 per cent ash insoluble in hydrochloric acid, and
  (iii) 13 per cent moisture; and
(b) not less than 3 millilitres volatile oil per 100 grams of spice.

B.07.007. [S]. Cayenne Pepper or **Cayenne**, whole or ground,

(a) shall be the dried ripe fruit of *Capsicum frutescens L.*, *Capsicum baccatum L.*, or other small-fruited species of Capsicum and shall contain not more than
15-12-83
(i) 1.5 per cent starch,
(ii) 28 per cent crude fibre,
(iii) 10 per cent total ash,
(iv) 1.5 per cent ash insoluble in hydrochloric acid, and
(v) 10 per cent moisture; and

(b) may contain silicon dioxide as an anti-caking agent in an amount not exceeding 2.0 per cent.

B.07.008. [S]. Celery Salt

(a) shall be a combination of
(i) ground celery seed or ground dehydrated celery, and
(ii) salt in an amount not exceeding 75 per cent; and

(b) may contain silicon dioxide as an anticaking agent in an amount not exceeding 0.5 per cent.

B.07.009. [S]. Celery Seed, whole or ground, shall be the dried ripe fruit of *Apium graveolens L.* and shall contain

(a) not more than
(i) 12 per cent total ash,
(ii) 2 per cent ash insoluble in hydrochloric acid, and
(iii) 10 per cent moisture; and

(b) not less than 1.5 millilitres volatile oil per 100 grams of spice.

B.07.010. [S]. Celery Pepper

(a) shall be a combination of
(i) ground celery seed or ground dehydrated celery, and
13-9-79
(ii) ground black pepper in an amount not exceeding 70 per cent; and

(b) may contain silicon dioxide as an anticaking agent in an amount not exceeding 0.5 per cent.

B.07.011. [S]. Cinnamon or **Cassia**, whole or ground, shall be the dried bark of trees of the genus *Cinnamomum* of species *C. burmanni Blume, C. loureirii Nees* or *C. Cassia Blume* and shall contain

(a) not more than
(i) 6 per cent total ash,
(ii) 2 per cent ash insoluble in hydrochloric acid, and
(iii) 13 per cent moisture; and

(b) not less than 1.2 millilitres volatile oil per 100 grams of spice.

B.07.012. [S]. Ceylon Cinnamon, whole or ground, shall be cinnamon obtained exclusively from *Cinnamomum zeylanicum Nees.*

B.07.013. [S]. Cloves, whole or ground, shall be the dried unopened flower buds of *Eugenia caryophyllus (Spreng)* and shall contain

(a) not more than
(i) 5 per cent clove stems,
(ii) 6 per cent total ash,
(iii) 0.5 per cent ash insoluble in hydrochloric acid,
(iv) 10 per cent crude fibre, and
(v) 8 per cent moisture; and

(b) not less than 13 millilitres volatile oil per 100 grams of spice.

*(R) Minor correction

B.07.014. [S]. Coriander or **Coriander Seed**, whole or ground, shall be the dried fruit of *Coriandrum sativum L.* and shall contain

(a) not more than
  (i) 7 per cent total ash,
  (ii) 1 per cent ash insoluble in hydrochloric acid, and
  (iii) 9 per cent moisture; and
(b) not less than 0.3 millilitre volatile oil per 100 grams of spice.

B.07.015. [S]. Cumin or **Cumin Seed**, whole or ground, shall be the dried seeds of *Cuminum cyminum L.* and shall contain

(a) not more than
  (i) 9.5 per cent total ash,
  (ii) 1.5 per cent ash insoluble in hydrochloric acid, and
  (iii) 9 per cent moisture; and
(b) not less than 2.5 millilitres volatile oil per 100 grams of spice.

B.07.016. [S]. Curry Powder shall be any combination of

(a) turmeric with spices and seasoning; and
(b) salt in an amount not exceeding 5 per cent.

B.07.017. [S]. Dill Seed, whole or ground, shall be the dried fruit of *Anethum graveolens L.*, or *Anethum sowa D.C.* and shall contain

(a) not more than
  (i) 10 per cent total ash,
13-9-79 (ii) 2 per cent ash insoluble in hydrochloric acid, and
  (iii) 9 per cent moisture; and
(b) not less than 2 millilitres volatile oil per 100 grams of spice.

B.07.018. [S]. Fennel or **Fennel Seed**, whole or ground, shall be the dried ripe fruit of *Foeniculum vulgare Mill.* and shall contain

(a) not more than
  (i) 10 per cent total ash,
  (ii) 1 per cent ash insoluble in hydrochloric acid, and
  (iii) 10 per cent moisture; and
(b) not less than 1 millilitre volatile oil per 100 grams of spice.

B.07.019. [S]. Fenugreek, whole or ground, shall be the dried ripe fruit of *Trigonella foenumgraecum L.* and shall contain not more than

(a) 5 per cent total ash;
(b) 1 per cent ash insoluble in hydrochloric acid; and
(c) 10 per cent moisture.

B.07.020. [S]. Garlic Salt

(a) shall be a combination of
  (i) powdered dehydrated garlic, and
  (ii) salt in an amount not exceeding 75 per cent; and
(b) may contain one or more of the following anticaking agents in a total amount not exceeding 2 per cent: calcium aluminum silicate, calcium phosphate tribasic, calcium silicate, calcium stearate, magnesium carbonate, magnesium silicate, magnesium stearate, silicone dioxide in an amount not exceeding 1 per cent and sodium aluminum silicate.

B.07.021. [S]. Ginger whole or ground, shall be the washed and dried or decorticated rhizome of *Zingiber officinale Roscoe* and shall contain

(a) not more than
  (i) 7 per cent total ash,
  (ii) 1 per cent ash insoluble in hydrochloric acid, and
  (iii) 12.5 per cent moisture; and

(b) not less than 1.5 millilitres volatile oil per 100 grams of spice.

B.07.022. [S]. Mace, whole or ground, shall be the dried arillus of *Myristica fragrans Houttyn* and shall contain

(a) not more than
  (i) 3.5 per cent total ash,
  (ii) 0.5 per cent ash insoluble in hydrochloric acid, and
  (iii) 8 per cent moisture, and

(b) not less than 11 millilitres volatile oil per 100 grams of spice,

and the total non-volatile extracts obtainable therefrom by

(c) ethyl ether, shall not be less than 20 per cent nor more than 35 per cent, and

(d) ethyl ether, after preliminary extraction with petroleum ether, shall not exceed 5 per cent.

13-9-79

B.07.023. [S]. Marjoram, whole or ground, shall be the dried leaves, with or without a small proportion of the flowering tops, of *Marjorana hortensis Moench* and shall contain

(a) not more than
  (i) 10 per cent stems and foreign material of plant origin,
  (ii) 13.5 per cent total ash,
  (iii) 4.5 per cent ash insoluble in hydrochloric acid, and
  (iv) 10 per cent moisture; and

(b) not less than 0.7 millilitre volatile oil per 100 grams of spice.

B.07.024. [S]. Mustard Seed shall be the seed of *Sinapis alba, Brassica hirta Moench, Brassica juncea (L) Cosson* or *Brassica nigra* and shall contain

(a) not more than
  (i) 7 per cent total ash,
  (ii) 1 per cent ash insoluble in hydrochloric acid, and
  (iii) 11 per cent moisture; and

(b) not less than 25 per cent non-volatile ether extract.

B.07.025. [S]. Mustard, Mustard Flour or **Ground Mustard** shall be powdered mustard seed

(a) made from mustard seed from which
  (i) most of the hulls have been removed, and
  (ii) a portion of the fixed oil may have been removed; and

(b) that contains not more than
  (i) 1.5 per cent starch, and
  (ii) 8 per cent total ash, on an oil-free basis.

B.07.026. [S]. Nutmeg, whole or ground, shall be the dried seed of *Myristica fragrans Houttyn* and may, prior to grinding, have a thin coating of lime and shall contain

(a) not more than
  (i) 3 per cent total ash,
  (ii) 0.5 per cent ash insoluble in hydrochloric acid, and
  (iii) 8 per cent moisture; and

(b) not less than
(i) 25 per cent non-volatile ether extract, and
(ii) 6.5 millilitres volatile oil per 100 grams of spice.

B.07.027. [S]. Onion Salt

(a) shall be a combination of
(i) powdered dehydrated onion, and
(ii) salt in an amount not exceeding 75 per cent; and

13-9-79 (b) may contain one or more of the following anticaking agents in a total amount not exceeding 2 per cent:

calcium aluminum silicate, calcium phosphate tribasic, calcium silicate, calcium stearate, magnesium carbonate, magnesium silicate, magnesium stearate, silicone dioxide in an amount not exceeding 1 per cent and sodium aluminum silicate.

B.07.028. [S]. Oregano, whole or ground, shall be the dried leaves of *Origanum vulgar L.* or *Origanum Spp.* and shall contain

(a) not more than
(i) 10 per cent total ash,
(ii) 2 per cent ash insoluble in hydrochloric acid, and
(iii) 10 per cent moisture; and

(b) not less than 2.5 millilitres volatile oil per 100 grams of spice.

B.07.029. [S]. Paprika shall be the dried, ground ripe fruit of *Capsicum annuum L.* and

15-12-83 (a) shall contain not more than
(i) 23 per cent crude fibre,
(ii) 8.5 per cent total ash,
(iii) 1 per cent ash insoluble in hydrochloric acid, and
(iv) 12 per cent moisture; and

(b) may contain silicon dioxide as an anti-caking agent in an amount not exceeding 2.0 per cent.

B.07.030. [S]. Black Pepper or **Peppercorn**, whole or ground, shall be the dried, immature berry of *Piper nigrum L.* and shall contain

(a) not more than
(i) 7 per cent total ash,
(ii) 1 per cent ash insoluble in hydrochloric acid, and
(iii) 12 per cent moisture;

(b) not less than
(i) 6 per cent non-volatile methylene chloride extract,
(ii) 30 per cent pepper starch, and
(iii) 2.0 millilitres volatile oil per 100 grams of spice; and

(c) when ground, all the parts of the berry in their normal proportions.

B.07.031. [S]. White Pepper, whole or ground, shall be the dried, mature berry of *Piper nigrum L.*, from which the outer coating is and the inner coating may be removed and shall contain

(a) not more than
(i) 5 per cent crude fibre,
(ii) 2.5 per cent total ash,
(iii) 0.3 per cent ash insoluble in hydrochloric acid, and
(iv) 15 per cent moisture; and

(b) not less than
(i) 6 per cent non-volatile methylene chloride extract,
(ii) 52 per cent pepper starch, and
(iii) 1 millilitre volatile oil per 100 grams of spice.

B.07.032. [S]. Poppy seed shall be the dried seed of *Papaver somniferum L.* and shall contain

(a) not more than
  (i) 7 per cent total ash, and
  (ii) 1 per cent ash insoluble in hydrochloric acid; and

(b) not less than 40 per cent non-volatile ether extract.

B.07.033. [S]. Rosemary, whole or ground, shall be the dried leaves of *Rosemarinus officinalis L.* and shall contain

(a) not more than
  (i) 7.5 per cent total ash,
  (ii) 1 per cent ash insoluble in hydrochloric acid, and
  (iii) 9 per cent moisture; and

(b) not less than 1.2 millilitres volatile oil per 100 grams of spice.

B.07.034. [S]. Sage, whole or ground, shall be the dried leaves of the sage plant *Salvia officinalis L.*, *Salvia triloba L.* or *Salvia lavandulaefolia Vahl.* and shall contain

13-9-79

(a) not more than
  (i) 12 per cent stems excluding petioles and foreign material of plant origin,
  (ii) 10 per cent total ash,
  (iii) 1 per cent ash insoluble in hydrochloric acid, and
  (iv) 10 per cent moisture; and

(b) not less than 1 millilitre volatile oil per 100 grams of spice.

B.07.035. [S]. Savory, whole or ground, shall be the dried leaves and flowering tops of *Satureja hortensis L.* or *Satureja montana L.* and shall contain

(a) not more than
  (i) 11 per cent total ash,
  (ii) 2 per cent ash insoluble in hydrochloric acid, and
  (iii) 14 per cent moisture; and

(b) not less than 0.8 millilitre volatile oil per 100 grams of spice.

B.07.036. [S]. Sesame Seed shall be the dried hulled seed of *Sesamum indicum L.* and shall contain

(a) not more than 8 per cent moisture; and
(b) not less than 50 per cent non-volatile ether extract.

B.07.037. [S]. Tarragon, whole or ground, shall be the dried leaves and flowering tops of *Artemisia dracunculus L.* and shall contain

(a) not more than
  (i) 15 per cent total ash,
  (ii) 1.5 per cent ash insoluble in hydrochloric acid, and
  (iii) 10 per cent moisture; and

(b) not less than 0.3 millilitre volatile oil per 100 grams of spice.

B.07.038. [S]. Thyme, whole or ground, shall be the dried leaves and flowering tops of the thyme plant *Thymus vulgaris L.* or *Thymus Zugis L.* and shall contain

(a) not more than
  (i) 12 per cent total ash,
  (ii) 5 per cent ash insoluble in hydrochloric acid, and
  (iii) 9 per cent moisture; and

(b) not less than 0.9 millilitre volatile oil per 100 grams of spice.

B.07.039. [S]. Turmeric, whole or ground, shall be the dried rhizome of *Curcuma longa L.* and shall contain

(a) not more than
  (i) 7 per cent total ash,
  (ii) 1.5 per cent ash insoluble in hydrochloric acid, and
  (iii) 10 per cent moisture; and

(b) not less than 3.5 millilitres volatile oil per 100 grams of spice.

B.07.040. [S]. Mayonnaise, Mayonnaise Dressing or **Mayonnaise Salad Dressing**

(a) shall be a combination of
  (i) vegetable oil,
  (ii) whole egg or egg yolk, in liquid, frozen or dried form, and
  (iii) vinegar or lemon juice;

(b) may contain
  (i) water,
  (ii) salt,
  (iii) a sweetening agent,
  (iv) spice or other seasoning except turmeric or saffron,
  (v) citric, tartaric or lactic acid, and
  (vi) a sequestering agent; and

(c) shall contain not less than 65 per cent vegetable oil.

B.07.041. [S]. French Dressing

(a) shall be a combination of
  (i) vegetable oil, and
13-9-79 (ii) vinegar or lemon juice;

(b) may contain
  (i) water,
  (ii) salt,
  (iii) a sweetening agent,
  (iv) spice, tomato or other seasoning,
  (v) an emulsifying agent,
  (vi) whole egg or egg yolk, in liquid, frozen or dried form,
  (vii) citric, tartaric or lactic acid, and
  (viii) a sequestering agent; and

(c) shall contain not less than 35 per cent vegetable oil.

B.07.042. [S]. Salad Dressing

(a) shall be a combination of
  (i) vegetable oil,
  (ii) whole egg or egg yolk, in liquid, frozen or dried form,
  (iii) vinegar or lemon juice, and
  (iv) starch, flour, rye flour or tapioca flour or any combination thereof;

(b) may contain
  (i) water,
  (ii) salt,
  (iii) a sweetening agent,
  (iv) spice or other seasoning,
  (v) an emulsifying agent,
  (vi) citric, tartaric or lactic acid, and
  (vii) a sequestering agent; and

(c) shall contain not less than 35 per cent vegetable oil.

B.07.043. No person shall sell a dressing that contains more than 5 per cent C_{22} Monoenoic Fatty Acids calculated as a proportion of the total fatty acids contained in the dressing.

Dairy Products

4-10-65 **B.08.001.** The foods referred to in this DIVISION are dairy products.

B.08.001.1 In this Division, "milk product" means

(a) with respect to butter, whey butter or cheese, any of the following products, namely,
  (i) partly skimmed milk, skim milk, cream, buttermilk and whey cream, and
  (ii) milk in concentrated, dried or reconstituted form and any product referred to in subparagraph (i) in concentrated, dried or reconstituted form,

18-6-92 (b) with respect to cream cheese spread, cream cheese spread with named added ingredients, processed cheese food, processed cheese food with named added ingredients, processed cheese spread, processed cheese spread with named added ingredients, cold-pack cheese food or cold-pack cheese food with named added ingredients, any of the following products, namely,
  (i) butter, whey butter and whey, and
  (ii) any product referred to in subparagraph (i) in concentrated or dried form, including whey protein concentrate, and

(c) with respect to ice milk mix, ice cream mix or sherbet, any of the products referred to in subparagraph (a)(i) or (ii) or (b)(i) or (ii). (*produit du lait*)

B.08.002. Except as provided in these regulations, a dairy product that contains a fat other than milk fat is adulterated.

27-6-85 **B.08.002.1** Sections B.08.003 to B.08.028 do not apply to a lacteal secretion obtained from the mammary gland of any animal other than a cow, genus *Bos*. or a product or derivative of such secretion.

17-10-95 **B.08.002.2** (1) Subject to subsection (2), no person shall sell the normal lacteal secretion obtained from the mammary gland of the cow, genus *Bos*, or of any other animal, or sell a dairy product made with any such secretion, unless the secretion or dairy product has been pasteurized by being held at a temperature and for a period that ensure the reduction of the alkaline phosphatase activity so as to meet the tolerances specified in official method MFO-3, *Determination of Phosphatase Activity in Dairy Products*, dated November 30, 1981.

(2) Subsection (1) does not apply to

19-9-91 (a) cheese; or

(b) any food that is sold for further manufacturing or processing in order to pasteurize it in the manner described in subsection (1).

Milk

B.08.003. [S]. Milk or **Whole Milk**

17-10-95 (a) shall be the normal lacteal secretion obtained from the mammary gland of the cow, genus *Bos*; and

25-11-75 (b) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

B.08.004. [S]. Skim Milk

16-8-78 (a) shall be milk that contains not more than 0.3 per cent milk fat;

25-11-75 (b) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A; and

(c) shall contain vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

25-3-65 **B.08.005. [S]. Partly Skimmed Milk** or **Partially Skimmed Milk**

16-8-78 (a) shall be derived from milk that has had its fat content reduced by mechanical separation or adjusted by the addition of cream, milk, partly skimmed milk or skim milk, either singly or in combination;

(b) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A, in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A; and

25-11-75 (c) shall contain vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

3-9-64 **B.08.006. [S]. Milk Fat** or **Butter Fat** shall be the fat of cow's milk, and shall have

(a) a specific gravity of not less than 0.905 at a temperature of 40°C.,

5-8-82 (b) a tocopherol content not greater than 50 micrograms per gram, as determined by official method FO-16, Determination of Tocopherol in Milk Fat or Butter Fat, October 15, 1981,

(c) a Reichert-Meissl number not less than 24, and

(d) a Polenske number not exceeding 10 per cent of the Reichert-Meissl number and in no case shall the Polenske number exceed 3.5, and

where the tocopherol content is greater than 50 micrograms per gram or the Polenske number exceeds 10 per cent of the Reichert-Meissl number, there shall be deemed to have been an addition to the milk fat of fat other than of cow's milk.

B.08.007. [S]. Sterilized Milk

(a) repealed by P.C. 1997-378 of March 19, 1997;

19-3-97 (b) repealed by P.C. 1997-378 of March 19, 1997;

25-11-75 (c) shall contain not less than

(i) 11.75 per cent milk solids, and

(ii) 3.25 per cent milk fat; and

(d) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of Vitamin D.

B.08.008. The percentage of milk fat contained in

(a) partly skimmed milk or partially skimmed milk,

20-1-77 (b) partly skimmed milk with added milk solids or partially skimmed milk with added milk solids, or

(c) evaporated partly skimmed milk or concentrated partly skimmed milk,

shall be shown on the principal display panel followed by the words "milk fat" or the abbreviation "B.F." or "M.F.".

B.08.009. [S]. Condensed Milk or **Sweetened Condensed Milk** shall be milk from which water has been evaporated and to which has been added sugar, dextrose, glucose, glucose solids or lactose, or any combination thereof, may contain added vitamin D and shall contain not less than

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(a) 28 per cent milk solids, and

(b) 8 per cent milk fat.

16-8-78 **B.08.010. [S]. Evaporated Milk**

25-11-75 (a) shall be milk from which water has been evaporated;

(b) shall contain not less than

18-6-92 (i) 25.0 per cent milk solids, and

(ii) 7.5 per cent milk fat;

(c) shall, notwithstanding sections D.01.009 to D.01.011, contain added vitamin C in such an amount that a reasonable daily intake of the milk contains not less than 60 milligrams and not more than 75 milligrams of vitamin C;

(d) shall contain vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and

25-11-75 (e) may contain

(i) added disodium phosphate or sodium citrate, or both, and

(ii) an emulsifying agent.

B.08.011. [S]. Evaporated Skim Milk or **Concentrated Skim Milk**

(a) shall be milk that has been concentrated to at least one-half of its original volume by the removal of water;
(b) shall contain
  (i) not more than 0.3 per cent milk fat, and
  (ii) not less than 17.0 per cent milk solids other than fat;
25-11-75 (c) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A;
(d) shall, notwithstanding sections D.01.009 to D.01.011, contain added vitamin C in such an amount that a reasonable daily intake of the milk contains not less than 60 milligrams and not more than 75 milligrams of vitamin C;
25-11-75 (e) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and
(f) may contain added disodium phosphate or sodium citrate, or both.

B.08.012. [S]. Evaporated Partly Skimmed Milk or **Concentrated Partly Skimmed Milk**

(a) shall be milk from which part of the milk fat has been removed;
(b) shall be concentrated to at least one-half its original volume by the removal of water;
4-10-73 (c) shall contain not less than 17.0 per cent milk solids other than fat; and
(d) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A;
25-11-75 (e) shall, notwithstanding sections D.01.009 to D.01.011, contain added vitamin C in such an amount that a reasonable daily intake of the milk contains not less than 60 milligrams and not more than 75 milligrams of vitamin C;
(f) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and
(g) may contain
  (i) an emulsifying agent, and
  (ii) added disodium phosphate or sodium citrate, or both.

16-8-78 **B.08.013. [S]. Milk Powder, Whole Milk Powder, Dry Whole Milk,** or **Powdered Whole Milk**

(a) shall be dried milk;
3-9-64 (b) shall contain not less than
  (i) 95 per cent milk solids, and
  (ii) 26 per cent milk fat;
25-11-75 (c) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and
8-12-83 (d) may contain the emulsifying agent lecithin in an amount not exceeding 0.5%.

16-8-78 **B.08.014. [S]. Skim Milk Powder** or **Dry Skim Milk**

25-3-65 (a) shall be dried skim milk;
(b) shall contain not less than 95 per cent milk solids; and
25-11-75 (c) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A;
(d) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and
(e) may contain an anti-foaming agent.

5-8-82 **B.08.014A.** No person shall sell milk powder, whole milk powder, dry whole milk, powdered whole milk, skim milk powder or dry skim milk unless it is free from bacteria of the genus *Salmonella*, as determined by official method MFO-12, Microbiological Examination of Milk Powder, November 30, 1981.

13-5-75 **B.08.015.** No person shall sell milk, skim milk, partly skimmed milk, (naming the flavour) milk, (naming the flavour) skim milk, (naming the flavour) partly skimmed milk, skim milk with added milk solids, partly skimmed milk with added milk solids, (naming the flavour) skim milk with added milk solids, (naming the flavour) partly skimmed milk with added milk solids, condensed milk, evaporated milk, evaporated skim milk, evaporated partly skimmed milk, milk powder or skim milk powder, in which the vitamin content has been increased by either irradiation or addition unless

25-3-65 (a) in the case of the addition of vitamin D, the menstruum containing the vitamin D contributes not more than 0.01 per cent fat foreign to milk;

23-6-88 (b) in cases where the vitamin D content is increased by irradiation, the principal display panel of the label carries the statement "Vitamin D Increased" immediately preceding or following the name of the food without intervening written, printed or graphic matter.

20-1-77 (c) Revoked by P.C. 1977-68 of January 20, 1977.

B.08.016. [S]. (naming the flavour) Milk

(a) shall be the product made from

16-7-74 (i) milk, milk powder, skim milk, skim milk powder, partly skimmed milk, evaporated milk, evaporated partly skimmed milk, evaporated skim milk or cream or any combination thereof,

(ii) a flavouring preparation, and

(iii) a sweetening agent;

25-11-75 (b) shall contain not less than 3.0 per cent milk fat;

(c) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D;

12-9-84 (d) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch; and

5-8-82 (e) may contain not more than 50,000 total aerobic bacteria per cubic centimetre, as determined by official method MFO-7, Microbiological Examination of Milk, November 30, 1981.

B.08.017. [S]. (naming the flavour) Skim Milk

(a) shall be the product made from

16-7-74 (i) skim milk, skim milk powder or evaporated skim milk or any combination thereof,

(ii) a flavouring preparation, and

(iii) a sweetening agent;

23-6-88 (b) shall contain not more than 0.3 per cent milk fat;

25-11-75 (c) shall notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A;

(d) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and

12-9-84 (e) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch.

B.08.018. [S]. (naming the flavour) Partly (Partially) Skimmed Milk

16-7-74 (a) shall be the product made from

(i) milk, milk powder, skim milk, skim milk powder, partly skimmed milk, evaporated milk, evaporated partly skimmed milk, evaporated skim milk or cream or any combination thereof,

(ii) a flavouring preparation, and

(iii) a sweetening agent;

16-8-78 (b) shall contain more than 0.3 per cent and less than 3.0 per cent milk fat;

(c) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A;

25-11-75 (d) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D;

12-9-84 (e) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch; and

5-8-82 (f) may contain not more than 50,000 total aerobic bacteria per cubic centimetre, as determined by official method MFO-7, Microbiological Examination of Milk, November 30, 1981.

B.08.019. [S]. Skim Milk with Added Milk Solids

(a) shall be skim milk to which has been added skim milk powder or evaporated skim milk or both;
(b) shall contain not less than 10 per cent milk solids;
16-8-78 (c) shall contain not more than 0.3 per cent milk fat;
(d) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the dairy product contains not less than 1200 International Units and not more than 2500 International Units of vitamin A; and
25-11-75 (e) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

16-7-74 **B.08.020. [S]. Partly Skimmed Milk with Added Milk Solids** or **Partially Skimmed Milk with Added Milk Solids**

(a) shall be partly skimmed milk to which has been added skim milk powder, milk powder, evaporated milk, evaporated partly skimmed milk or evaporated skim milk or any combination thereof,
(b) shall contain not less than 10 per cent milk solids not including fat; and
(c) shall, notwithstanding section D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A; and
25-11-75 (d) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

B.08.021. [S]. Malted Milk or **Malted Milk Powder**

(a) shall be the product made by combining milk with the liquid separated from a mash of ground barley malt and meal;
(b) may have added to it, in such manner as to secure the full enzyme action of the malt extract, salt and sodium bicarbonate or potassium bicarbonate;
(c) may have water removed from it; and
(d) shall contain
(i) not less than 7.5 per cent milk fat, and
(ii) not more than 3.5 per cent moisture.

12-9-84 **B.08.022. [S]. (naming the flavour) Malted Milk** or **(naming the flavour) Malted Milk Powder**

(a) shall be malted milk or malted milk powder containing a flavouring preparation; and
(b) may contain lactase.

B.08.023. [S]. (naming the flavour) Skim Milk with Added Milk Solids

(a) shall be the product made from
16-7-74 (i) skim milk, skim milk powder, or evaporated skim milk or any combination thereof,
(ii) a flavouring preparation, and
(iii) a sweetening agent;
(b) shall contain not less than 10 per cent milk solids not including fat;
16-8-78 (c) shall contain not more than 0.3 per cent milk fat;
(d) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A;
25-11-75 (e) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and
12-9-84 (f) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch.

11-7-63 **B.08.024.** No person shall sell milk for manufacture into dairy products if it contains more than

(a) 2,000,000 total aerobic bacteria per millilitre, as determined by official method MFO-7, Microbiological Examination of Milk, November 30, 1981; or
5-8-82 (b) two milligrams of sediment per 16 fluid ounces, as determined by official method MFO-8, Determination of Sediment in Milk, November 30, 1981.

11-7-63 **B.08.025.** No manufacturer shall purchase milk for manufacture or manufacture milk into other dairy products if he has reason to believe it does not meet the requirements of section B.08.024.

B.08.026. [S]. (naming the flavour) Partly (Partially) Skimmed Milk with Added Milk Solids

16-7-74 (a) shall be the product made from
(i) milk, milk powder, skim milk, skim milk powder, partly skimmed milk, evaporated milk, evaporated partly skimmed milk, evaporated skim milk or cream or any combination thereof,
(ii) a flavouring preparation, and
(iii) a sweetening agent;
(b) shall contain not less than 10 per cent milk solids not including fat;
16-8-78 (c) shall contain more than 0.3 per cent and less than 3.0 per cent milk fat;
(d) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1200 International Units and not more than 2500 International Units of vitamin A;
(e) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D;
12-9-84 (f) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch; and
5-8-82 (g) may contain not more than 50,000 total aerobic bacteria per cubic centimetre, as determined by official method MFO-7, Microbiological Examination of Milk, November 30, 1981.

16-8-78 **B.08.027.** Notwithstanding anything contained in these Regulations, the following dairy products that are used in or sold for the manufacture of other foods are not required to contain added vitamins: milk; partly skimmed milk; partially skimmed milk; skim milk; sterilized milk; evaporated milk; evaporated skim milk; concentrated skim milk; evaporated partly skimmed milk; concentrated partly skimmed milk; milk powder; dry whole milk; powdered whole milk; skim milk powder; dry skim milk; partly skimmed milk powder; partially skimmed milk powder; skim milk with added milk solids; partly skimmed milk with added milk solids; and partially skimmed milk with added milk solids.

31-10-88 **B.08.028.** (1) The percentage of milk fat contained in

(a) (naming the flavour) milk,
(b) (naming the flavour) partly (partially) skimmed milk,
21-12-78 (c) (naming the flavour) partly (partially) skimmed milk with added milk solids,
(d) cream, and
(e) sour cream,
shall be shown on the principal display panel, followed by the words "milk fat" or the abbreviation "B.F." or "M.F.".

31-10-88 (2) In addition to the statement referred to in subsection (1), a person may, on the label of a food referred to in that subsection, make a declaration of the fat content of the food, expressed in grams per serving of stated size.

Goat's Milk

B.08.028.1 A lacteal secretion obtained from the mammary gland of any animal other than a cow, genus *Bos*, and a product or derivative of such secretion shall be labelled so as to identify that animal.

B.08.029. (1) Notwithstanding sections D.01.009 to D.01.011, no person shall sell goat's milk or goat's milk powder to which vitamin D has been added unless the goat's milk or goat's milk powder contains not less than 35 International Units and not more than 45 International Units of vitamin D per 100 mL of the food when ready-to-serve.

27-6-85 (2) Notwithstanding sections D.01.009 to D.01.011, no person shall sell partly skimmed goat's milk, skimmed goat's milk, partly skimmed goat's milk powder or skimmed goat's milk powder to which vitamins have been added unless the product contains not less than 35 International Units of vitamin D and 140 International Units of vitamin A and not more than 45 International Units of vitamin D and 300 International Units of vitamin A per 100 mL of food when ready-to-serve.

(3) Notwithstanding sections D.01.009 to D.01.011, no person shall sell evaporated goat's milk to which vitamins have been added unless 100 mL of the evaporated goat's milk, when reconstituted according to directions for use, contains not less than 7 milligrams of vitamin C, 35 International Units of vitamin D and 10 micrograms of folic acid and not more than 9 milligrams of vitamin C, 45 International Units of vitamin D and 20 micrograms of folic acid.

(4) Notwithstanding sections D.01.009 to D.01.011, no person shall sell evaporated partly skimmed goat's milk or evaporated skimmed goat's milk to which vitamins have been added unless 100 mL of the evaporated partly skimmed goat's milk or the evaporated skimmed goat's milk, when reconstituted according to directions for use, contains not less than 140 International Units of vitamin A, 7 milligrams of vitamin C, 35 International Units of vitamin D and 10 micrograms of folic acid and not more than 300 International Units of vitamin A, 9 milligrams of vitamin C, 45 International Units of vitamin D and 20 micrograms of folic acid.

Cheese

18-6-92 **B.08.030.** (1) In this Division, when used with respect to cheese,

5-8-82 "pasteurized source" means milk, skim milk, cream, reconstituted milk powder, reconstituted skim milk powder or any combination thereof that has been pasteurized by being held at a temperature of not less than 61.6°C for a period of not less than 30 minutes, or for a time and a temperature that is equivalent thereto in phosphatase destruction as determined by official method MFO-3, Determination of Phosphatase Activity in Dairy Products, November 30, 1981; (*matière première pasteurisée*)
"pickles and relishes" means foods that meet the standard prescribed in section B.11.051; (*cornichons et achards*)
"stored" means to have been kept or held at a temperature of 2°C or more for a period of 60 days or more from the date of the beginning of the manufacturing process; (entreposé)
"whole" means of the original size and shape as manufactured. (*entier*)

(2) The word "process" may be used in the place of the word "processed" in the following common names: processed (naming the variety) cheese, processed (naming the variety) cheese with (naming the added ingredients), processed cheese food, processed cheese food with (naming the added ingredients), processed cheese spread, and processed cheese spread with (naming the ingredients).

B.08.031. A cheese made from milk that is the normal lacteal secretion of the mammary gland of animals other than the cow, genus *Bos*, shall

18-10-79 (a) conform to all requirements in this Division applicable to the variety; and
(b) be labelled to show the source of the milk on the principal display panel.

B.08.032. (1) Each of the following foods for which a standard is prescribed, namely,
(a) (named variety) cheese,
(b) cheddar cheese,
(c) cream cheese,
(d) whey cheese,
(e) (named variety) whey cheese,
(f) cream cheese with (named added ingredients),
(g) cream cheese spread,
(h) cream cheese spread with (named added ingredients),
(i) processed (named variety) cheese,
(j) processed (named variety) cheese with (named added ingredients),
(k) processed cheese food,
(l) processed cheese food with (named added ingredients),
(m) processed cheese spread,
(n) processed cheese spread with (named added ingredients),
(o) cold-pack (named variety) cheese,
(p) cold-pack (named variety) cheese with (named added ingredients),
(q) cold-pack cheese food, and
(r) cold-pack cheese food with (named added ingredients),
shall be labelled to show on the principal display panel a statement of the percentage of milk fat in the food followed by the words "milk fat" or the abbreviation "B.F." or "M.F.", and the percentage of moisture in the food followed by the word "moisture" or "water".

31-10-88 (2) Subject to subsection (3), no person shall make any direct or indirect reference on the label of a food referred to in subsection (1) to the milk fat content or moisture content of the food except as required by subsection (1).

1-11-94 (3) In addition to the statements referred to in subsection (1), a person may, on the label of a food referred to in that subsection, make a declaration of the fat content of the food, expressed in grams per serving of a stated size.

B.08.033. (1) **[S]. (Naming the variety) Cheese** other than cheddar cheese, cream cheese, whey cheese, cream cheese with (named added ingredients), cream cheese spread, cream cheese spread with (named added ingredients), processed (named variety) cheese, processed (named variety) cheese with (named added ingredients), processed cheese food, processed cheese food with (named added ingredients), processed cheese spread, processed cheese spread with (named added ingredients), cold-pack (named variety) cheese, cold-pack (named variety) cheese with (named added ingredients), cold-pack cheese food, cold-pack cheese food with (named added ingredients), cottage cheese and creamed cottage cheese,

(a) shall
- (i) be the product made by coagulating milk, milk products or a combination thereof with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey,
- (ii) possess the physical, chemical and organoleptic properties typical for the variety,
- (iii) where it is a cheese of variety named in the Table to this section, contain no more than the maximum percentage of moisture shown in column II thereof for that variety,
- (iv) where it is a cheese of a variety named in Part I of the Table to this section, contain no less than the minimum percentage of milk fat shown in column III for that variety, and
- (v) where it is cheese of a variety named in Part II of the Table to this section, contain no more than the maximum percentage of milk fat shown in column III for that variety; and

(b) may contain
- (i) salt, seasonings, condiments and spices,
- (ii) flavouring preparations other than cheese flavouring,
- (iii) micro-organisms to aid further ripening,
- (iv) one or more of the following colouring agents:
  - (A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin or turmeric,
  - (B) in an amount not exceeding 35 parts per million, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate or a combination thereof, and
  - (C) in an amount not exceeding 0.10 parts per million, brilliant blue FCF in feta cheese only, 13-9-00
- (v) calcium chloride as a firming agent in an amount not exceeding 0.02 per cent of the milk and milk products used,
- (vi) paraffin wax as a coating in an amount consistent with good manufacturing practice,
- (vii) where potassium nitrate, sodium nitrate or a combination thereof are used for the purpose and in the manner described in subsection (2), residues of potassium nitrate, sodium nitrate or a combination thereof in an amount not exceeding 50 parts per million,
- (viii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and 18-10-79
- (ix) the following preservatives:
  - (A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,
  - (B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid,
  - (C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively, or
  - (D) natamycin applied to the surface of the cheese in an amount that does not exceed 20 parts per million or, if the cheese is grated or shredded, 10 parts per million, 8-4-97
- (x) in the case of grated or shredded cheese, calcium silicate, microcrystalline cellulose or cellulose, or a combination of them, as an anticaking agent, the total amount not to exceed 2.0 per cent, and 8-4-97
- (xi) carbon dioxide as a pH adjusting agent in milk for cheese production, in an amount consistent with good manufacturing practice. 1-03-01

(2) Potassium nitrate, sodium nitrate or a combination thereof may be used as a preservative in cheese providing the following requirements are met:

(a) the amount of the salt or combination of salts does not exceed 200 parts per million of the milk and milk products used to make the cheese;

(b) the cheese in which the preservative is used is
- (i) mold ripened cheese packed in a hermetically sealed container, or
- (ii) ripened cheese
  - (A) that contains not more than 68 per cent moisture on a fat free basis, and
  - (B) during the manufacture of which the lactic acid fermentation and salting was completed more than 12 hours after coagulation of the curd by enzymes; and

(c) the salting is, in the case of the cheese described in subparagraph (b)(ii), applied externally as a dry salt or in the form of a brine. 1-4-82

2-4-92 (3) No person shall use an enzyme other than

5-4-05 (a) milk coagulating enzymes derived from *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson), *Mucor pusillus Lindt* or *Aspergillus oryzae* RET-1 (pBoel777), aminopeptidase derived from *Lactococcus lactis*, Chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), Chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), protease derived from *Micrococcus caseolyticus*, pepsin, rennet or bovine rennet, in the manufacture of any cheese to which subsection (1) applies;

(b) lipase and enzymes described in paragraph (a), in the manufacture of Asiago cheese, Blue cheese, Caciocavallo cheese, Feta cheese and Provolone cheese;

2-6-94 (c) a milk coagulating enzyme derived from *Endothia parasitica* and enzymes described in paragraph (a), in the manufacture of Emmentaler (Emmental, Swiss) cheese, Mozzarella (Scamorza) cheese and Part Skim Mozzarella (Part Skim Scamorza) cheese;

(d) lipase, a milk coagulating enzyme derived from *Endothia parasitica* and enzymes described in paragraph (a), in the manufacture of Parmesan cheese and Romano cheese;

30-11-00 (e) protease derived from *Aspergillus oryzae*, in the manufacture of Colby cheese; and

(f) lysozyme derived from egg white.

27-7-90 (3.1) No person shall use an enzyme referred to in subsection (3) at a level of use above that consistent with good manufacturing practice.

(4) Where a flavouring preparation, other than a flavouring preparation that has been traditionally used in the variety, is added to a cheese as permitted in subsection (1), the words "with (naming the flavouring preparation)" shall be added to the common name on any label.

(5) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(6) Where a cheese is labelled as permitted in subsection (5), the word "smoked" shall be shown on the principal display panel.

TABLE

PART I

Item	Column I Variety of Cheese	Column II Maximum Percentage of Moisture	Column III Minimum Percentage of Milk Fat
1.	Asiago	40.0	30.0
2.	Baby Edam	47.0	21.0
3.	Baby Gouda	45.0	26.0
4.	Blue	47.0	27.0
5.	Butter (Butterkäse)	46.0	27.0
6.	Bra	36.0	26.0
7.	Brick	42.0	29.0
8.	Brie	54.0	23.0
9.	Caciocavallo	45.0	24.0
10.	Camembert (Carré de l'est)	56.0	22.0
11.	Canadian Style Brick	42.0	29.0
12.	Canadian Style Munster	46.0	27.0
13.	Colby	42.0	29.0
14.	Danbo	46.0	25.0
15.	Edam	46.0	22.0
16.	Elbo	46.0	25.0
17.	Emmentaler (Emmental, Swiss)	40.0	27.0
18.	Esrom	50.0	23.0
19.	Farmer's	44.0	27.0
20.	Feta	55.0	22.0
21.	Fontina	46.0	27.0
22.	Fynbo	46.0	25.0
23.	Gouda	43.0	28.0
24.	Gournay	55.0	33.0
25.	Gruyère	38.0	28.0
26.	Havarti	50.0	23.0
27.	Jack	50.0	25.0
28.	Kasseri	44.0	25.0
29.	Limburger	50.0	25.0
30.	Maribo	43.0	26.0
31.	Montasio	40.0	28.0
32.	Monterey (Monterey Jack)	44.0	28.0
33.	Mozzarella (Scamorza)	52.0	20.0
34.	Muenster (Munster)	50.0	25.0
35.	Neufchâtel	60.0	20.0
36.	Parmesan	32.0	22.0
37.	Part Skim Mozzarella (Part Skim Scamorza)	52.0	15.0
38.	Part Skim Pizza	48.0	15.0
39.	Pizza	48.0	20.0
40.	Provolone	45.0	24.0
41.	Romano (Sardo)	34.0	25.0
42.	St. Jorge	40.0	27.0
43.	Saint-Paulin	50.0	25.0
44.	Samsoë	44.0	26.0
45.	Tilsiter (Tilsit)	45.0	25.0
46.	Tybo	46.0	25.0

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PART II

Item	Column I Variety of Cheese	Column II Maximum Percentage of Moisture	Column III Maximum Percentage of Milk Fat
1.	Harzkase (Harzer Käse, Mainzer Käse)	55.0	3.0
2.	Skim Milk	55.0	7.0

*(R) Minor correction

B.08.034. (1) [S]. Cheddar Cheese

(a) shall

(i) be the product made by coagulating milk, milk products or a combination thereof with the aid of bacteria to form a curd and subjecting the curd to

(A) the cheddar process, or

(B) any process other than the cheddar process that produces a cheese having the same physical, chemical and organoleptic properties as those of cheese produced by the cheddar process, and

(ii) contain

(A) not more than 39 per cent moisture, and

(B) not less than 31 per cent milk fat; and

(b) may contain

(i) salt,

(ii) flavouring preparations other than cheese flavouring,

(iii) bacterial cultures to aid further ripening,

(iv) one or more of the following colouring agents:

27-7-83 (A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) calcium chloride as a firming agent in an amount not exceeding 0.02 per cent of the milk and milk products used,

(vi) wood smoke as a preservative in an amount consistent with good manufacturing practice,

(vii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or a combination thereof in an amount not exceeding 2,000 parts per million calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate or a combination thereof in an amount not exceeding 3,000 parts per million calculated as sorbic acid,

1-4-82 (C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million calculated as propionic acid and sorbic acid respectively, or

8-4-97 (D) natamycin applied to the surface of the cheese in an amount that does not exceed 20 parts per million or, if the cheese is grated or shredded, 10 parts per million, and

8-4-97 (viii) in the case of grated or shredded cheddar cheese, calcium silicate, microcrystalline cellulose or cellulose, or a combination of them, as an anticaking agent, the total amount not to exceed 2.0 per cent.

(2) No person shall, in the manufacture of the cheddar cheese, use any enzyme other than

5-4-05 (a) lipase, pepsin, rennet, milk coagulating enzymes derived from *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)), *Mucor pusillus Lindt* or *Aspergillus oryzae* RET-1 (pBoel777), aminopeptidase derived from *Lactococcus lactis*, Chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A) or Chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105);

(b) protease derived from *Aspergillus oryzae;* and

30-11-00 (c) lysozyme derived from egg white.

27-7-90 (2.1) No person shall use an enzyme referred to in subsection (2) at a level of use above that consistent with good manufacturing practice.

(3) Where a flavouring preparation is added to a cheese as permitted in subsection (1), the words "with (naming the flavouring preparation)" shall be added to the common name in any label.

18-10-79 (4) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(5) Where a cheese is labelled as permitted in subsection (4), the word "smoked" shall be shown on the principal display panel.

B.08.035. (1) [S]. Cream Cheese

(a) shall

(i) be the product made by coagulating cream with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey, and

(ii) contain

(A) not more than 55 per cent moisture, and

(B) not less than 30 per cent milk fat; and

(b) may contain

(i) cream added to adjust the milk fat content,

(ii) salt,

(iii) nitrogen to improve spreadability in an amount consistent with good manufacturing practice,

(iv) the following emulsifying, gelling, stabilizing and thickening agents:
ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or any combination thereof in an amount not exceeding 0.5 per cent, and

(v) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) No person shall use any enzyme

4-4-95 (a) other than Chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), Chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), pepsin or rennet in the manufacture of cream cheese; and

(b) at a level of use above that consistent with good manufacturing practice.

B.08.036. (1) [S]. Whey Cheese or (naming the variety) Whey Cheese

(a) shall be the product made by coagulating whey or concentrated whey with the aid of heat to form a curd and shaping the curd; and

(b) may contain

(i) microorganisms to aid further ripening,

(ii) added milk and milk products, and

(iii) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice.

(2) No person shall use, to aid coagulation of whey in the manufacture of whey cheese, a substance other than vinegar or sour whey.

B.08.037. (1) [S]. Cream Cheese with (naming the added ingredients)

(a) shall

(i) be the product made by coagulating cream with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey, and

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from cream cheese but not in amounts so large as to change the basic nature of the product:

(A) cheese other than cream cheese,

(B) seasonings, spices, flavouring preparations, condiments or chocolate,

(C) fruits, vegetables, pickles, relishes or nuts,

18-10-79 (D) prepared or preserved meat, or

(E) prepared or preserved fish, and

(iii) contain

(A) not more than 60 per cent moisture, and

(B) not less than 26 per cent milk fat; and

(b) may contain

(i) cream added to adjust the milk fat content,

(ii) salt,

(iii) nitrogen to improve spreadability in an amount consistent with good manufacturing practice,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) the following emulsifying gelling, stabilizing and thickening agents:
ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or any combination thereof in an amount not exceeding 0.5 per cent, and

(vi) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) No person shall use any enzyme

4-4-95 (a) other than Chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), Chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), pepsin or rennet in the manufacture of a product to which subsection (1) applies; and

(b) at a level of use above that consistent with good manufacturing practice.

B.08.038. (1) [S]. Cream Cheese Spread

(a) shall

(i) be the product made by coagulating cream with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey, and

(ii) contain

(A) added milk and milk products,

(B) not less than 51 per cent cream cheese,

(C) not more than 60 per cent moisture, and

(D) not less than 24 per cent milk fat; and

(b) may contain

(i) cream added to adjust the milk fat content,

(ii) salt, vinegar and sweetening agents,

(iii) nitrogen to improve spreadability in an amount consistent with good manufacturing practice,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

(A) ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent, and

18-10-79 (B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice, and

(vii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) No person shall use any enzyme

4-4-95 (a) other than Chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), Chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), pepsin or rennet in the manufacture of a product to which subsection (1) applies; and

(b) at a level of use above that consistent with good manufacturing practice.

B.08.039. (1) [S]. Cream Cheese Spread with (naming the added ingredients)

(a) shall

(i) be the product made by coagulating cream with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from cream cheese spread but not in amounts so large as to change the basic nature of the product:

(A) cheese other than cream cheese,

(B) seasonings, spices, flavouring preparation, condiments or chocolate,

(C) fruits, vegetables, pickles, relishes or nuts,

(D) prepared or preserved meat, or
(E) prepared or preserved fish, and

(iii) contain
(A) added milk and milk products,
(B) not more than 60 per cent moisture, and
(C) not less than 24 per cent milk fat; and

(b) may contain
(i) cream added to adjust the milk fat content,
(ii) salt, vinegar and sweetening agents,
(iii) nitrogen to improve spreadability in an amount consistent with good manufacturing practice,
(iv) one or more of the following colouring agents:
(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and
(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,
(v) the following emulsifying, gelling, stabilizing and thickening agents:
18-10-79 (A) ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent, and
(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,
(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice, and
(vii) the following preservatives:
(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,
(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or
(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

2-4-92 (2) No person shall use any enzyme
4-4-95 (a) other than Chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), Chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), pepsin or rennet in the manufacture of a product to which subsection (1) applies; and
(b) at a level of use above that consistent with good manufacturing practice.

B.08.040. (1) [S]. Processed (naming the variety) Cheese

(a) shall
(i) subject to subparagraph (ii), be the product made by comminuting and mixing the named variety or varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat,
(ii) in the case of processed cheddar cheese, be the product made by comminuting and mixing one or more of the following:
(A) cheddar cheese,
18-10-79 (B) stirred curd cheese,
(C) granular curd cheese, or
(D) washed curd cheese
into a homogeneous mass with the aid of heat,
(iii) have, where it is made from
(A) one variety of cheese, in which the maximum amount of moisture permitted is less than 40 per cent, or
(B) two or more varieties of cheese, in which the average maximum amount of moisture permitted is less than 40 per cent,

*(R) Minor correction

a moisture content that does not exceed, by more than 5 per cent, the amount referred to in clause (A) or (B), as the case may be, and a milk fat content that is not less, by more than 3 per cent, than the minimum milk fat content or average minimum milk fat content permitted for that variety or those varieties, as the case may be,

(iv) subject to subparagraph (v), have, where it is made from

(A) one variety of cheese, in which the maximum amount of moisture permitted is 40 per cent or more, or

(B) more than one variety of cheese, in which the average maximum amount of moisture permitted is 40 per cent or more,

a moisture content that does not exceed, by more than 3 per cent, the amount referred to in clause (A) or (B), as the case may be, and a milk fat content that is not less, by more than 2 per cent, than the minimum milk fat content or average minimum milk fat content permitted for that variety or those varieties, as the case may be, and

(v) in the case of processed skim milk cheese, contain not more than

(A) 55 per cent moisture, and

(B) 7 per cent milk fat; and

(b) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) in the case of processed skim milk cheese, added skim milk powder, buttermilk powder and whey powder,

(iv) salt, vinegar and sweetening agents,

(v) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(vi) the following emulsifying, gelling, stabilizing and thickening agents:

(A) sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate) in an amount not exceeding 0.5 per cent,

18-10-79 (B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(C) lecithin in an amount not exceeding 0.2 per cent, and

(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

13-6-91 (vi.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vii) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(viii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(ix) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.041. (1) [S]. Processed (naming the variety) Cheese with (naming the added ingredients)

(a) shall

(i) be the product made by comminuting and mixing the named variety or varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from processed (named variety) cheese but not in amounts so large as to change the basic nature of the product:
(A) flavouring preparations other than such preparations that resemble the flavour of the varieties of cheese used in the product,
(B) seasonings, spices, condiments or chocolate,
(C) fruits, vegetables, pickles, relishes or nuts,
(D) prepared or preserved meat, or
(E) prepared or preserved fish,

(iii) have, where it is made from
(A) one variety of cheese, in which the maximum amount of moisture permitted is less than 40 per cent, or
(B) more than one variety of cheese, in which the average maximum amount of moisture permitted is less than 40 per cent,
a moisture content that does not exceed by more than 5 per cent, the amount referred to in clause (A) or (B), as the case may be, and a milk fat content that is not less, by more than 3 per cent, than the minimum milk fat content or average minimum milk fat content permitted for that variety or those varieties, as the case may be, and

(iv) have, where it is made from
(A) one variety of cheese, in which the maximum amount of moisture permitted is 40 per cent or more, or
(B) more than one variety of cheese, in which the average maximum amount of moisture permitted is 40 per cent or more,
a moisture content that does not exceed, by more than 3 per cent, the amount referred to in clause (A) or (B), as the case may be, and a milk fat content that is not less, by more than 2 per cent, than the minimum milk fat content or average minimum milk fat content permitted for that variety or those varieties, as the case may be; and

(b) may contain
(i) water added to adjust moisture content,
(ii) added milk fat,
18-6-92 (iii) salt, vinegar and sweetening agents,
(iv) one or more of the following colouring agents:
18-10-79 (A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and
(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:
(A) sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate) in an amount not exceeding 0.5 per cent,
(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,
(C) lecithin in an amount not exceeding 0.2 per cent, and
(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

13-6-91 (v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,
(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and
(viii) the following preservatives:
(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,
(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or
(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.041.1 (1) [S]. Processed Cheese Food

(a) shall
- (i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat, and
- (ii) contain
  - (A) added milk or milk products,
  - (B) not less than 51 per cent cheese,
  - (C) not more than 46 per cent moisture, and
  - (D) not less than 23 per cent milk fat; and

(b) may contain

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- (i) water added to adjust the moisture content,
- (ii) added milk fat,

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- (iii) salt, vinegar and sweetening agents,
- (iv) one or more of the following colouring agents:
  - (A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and
  - (B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,
- (v) the following emulsifying, gelling, stabilizing and thickening agents:
  - (A) sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate) in an amount not exceeding 0.5 per cent,
  - (B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,
  - (C) lecithin in an amount not exceeding 0.2 per cent, and
  - (D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

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- (v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,
- (vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,
- (vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and
- (viii) the following preservatives:
  - (A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,
  - (B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or
  - (C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

18-10-79 (2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.041.2. (1) [S]. Processed Cheese Food with (naming the added ingredients)

(a) shall
- (i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat,
- (ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from processed cheese food but not in amounts so large as to change the basic nature of the product:

(A) seasonings, spices, flavouring preparations, condiments or chocolate,
(B) fruits, vegetables, pickles, relishes or nuts,
(C) prepared or preserved meat, or
(D) prepared or preserved fish, and

(iii) contain
(A) added milk or milk products,
(B) not more than 46 per cent moisture, and
(C) not less than 22 per cent milk fat; and

(b) may contain
(i) water added to adjust the moisture content,
(ii) added milk fat,
18-6-92 (iii) salt, vinegar and sweetening agents,
(iv) one or more of the following colouring agents:
(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and
(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,
(v) the following emulsifying, gelling, stabilizing and thickening agents:
(A) sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate) in an amount not exceeding 0.5 per cent,
(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,
(C) lecithin in an amount not exceeding 0.2 per cent, and
(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,
13-6-91 (v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,
(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,
(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and
(viii) the following preservatives:
(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,
(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or
(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

18-10-79 (3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.041.3. (1) [S]. Processed Cheese Spread

(a) shall
(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat, and
(ii) contain
(A) added milk or milk products,
(B) not less than 51 per cent cheese,
(C) not more than 60 per cent moisture, and
(D) not less than 20 per cent milk fat;
(b) may contain
(i) water added to adjust the moisture content,
(ii) added milk fat,
(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:
(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and
(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

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(A) ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,
(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,
(C) lecithin in an amount not exceeding 0.2 per cent, and
(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

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(v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,
(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and
(viii) the following preservatives:
(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,
(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or
(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

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(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.041.4. (1) [S]. Processed Cheese Spread with (naming the added ingredients)

(a) shall
(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat,
(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from processed cheese spread but not in amounts so large as to change the basic nature of the product:
(A) seasonings, spices, flavouring preparations, condiments or chocolate,
(B) fruits, vegetables, pickles, relishes or nuts,
(C) prepared or preserved meat, or
(D) prepared or preserved fish, and
(iii) contain
(A) added milk or milk products,
(B) not more than 60 per cent moisture, and
(C) not less than 20 per cent milk fat; and

(b) may contain
(i) water added to adjust the moisture content,
(ii) added milk fat,
(iii) salt, vinegar and sweetening agents,
(iv) one or more of the following colouring agents:
(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

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(A) ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,

(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(C) lecithin in an amount not exceeding 0.2 per cent, and

(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

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(v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

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(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.041.5. (1) [S]. Cold-Pack (naming the variety) Cheese

(a) shall

(i) subject to subparagraph (ii), be the product made by comminuting and mixing the named variety or varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass without the aid of heat,

(ii) in the case of cold-pack cheddar cheese, be the product made by comminuting and mixing one or more of the following:

(A) cheddar cheese,

(B) stirred curd cheese,

(C) granular curd cheese, or

(D) washed curd cheese

into a homogeneous mass without the aid of heat,

(iii) contain, where it is made from

(A) one variety of cheese, not more moisture and not less milk fat than the maximum moisture content and minimum fat content permitted for that variety, or

(B) more than one variety of cheese, not more moisture and not less milk fat than the average maximum moisture content and the average minimum fat content permitted for those varieties; and

(b) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

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(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vi) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(vii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.041.6. (1) [S] Cold-Pack (naming the variety) Cheese with (naming the added ingredients)

(a) shall

(i) be the product made by comminuting and mixing the named variety or varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass without the aid of heat,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from cold-pack (named variety) cheese but not in amounts so large as to change the basic nature of the product:

(A) flavouring preparations other than such preparations that resemble the flavour of the varieties of cheese used in the product,

(B) seasonings, spices, condiments or chocolate,

(C) fruits, vegetables, pickles, relishes or nuts,

(D) prepared or preserved meat, or

(E) prepared or preserved fish, and

(iii) contain, where it is made from

(A) one variety of cheese, not more moisture and not less milk fat than the maximum moisture content and one per cent less than the minimum milk fat content permitted for that variety, or

18-10-79 (B) more than one variety of cheese, not more moisture and not less milk fat than the average maximum moisture content and one per cent less than the average minimum milk fat content permitted for those varieties; and

(b) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

18-6-92 (iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents: ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.041.7. (1) [S]. Cold-Pack Cheese Food

(a) shall

(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass without the aid of heat,

(ii) contain

(A) added milk or milk products,

(B) not less than 51 per cent cheese,

(C) not more than 46 per cent moisture, and

(D) not less than 23 per cent milk fat; and

(b) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

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(v) the following emulsifying, gelling, stabilizing and thickening agents:
ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.041.8. (1) [S]. Cold-Pack Cheese Food with (naming the added ingredients)

(a) shall

(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass without the aid of heat,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from cold-pack cheese food but not in amounts so large as to change the basic nature of the product:
(A) seasonings, spices, flavouring preparations, condiments or chocolate,
(B) fruits, vegetables, pickles, relishes or nuts,
(C) prepared or preserved meat, or
(D) prepared or preserved fish, and

(iii) contain
(A) added milk or milk products,
(B) not more than 46 per cent moisture, and
(C) not less than 22 per cent milk fat; and

(b) may contain
(i) water added to adjust the moisture content,
(ii) added milk fat,
(iii) salt and vinegar, sweetening agents,
(iv) one or more of the following colouring agents:
(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and
(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

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(v) the following emulsifying, gelling, stabilizing and thickening agents:
ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,
(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,
(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and
(viii) the following preservatives:
(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,
(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or
(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word "smoked" shall be shown on the principal display panel.

B.08.042. No manufacturer shall sell whole cheese that is not made from a pasteurized source unless the date of the beginning of the manufacturing process is

(a) marked or branded thereon within three days thereof or
(b) marked on the label at the time of packaging, if the cheese is such that, because of its texture, consistency, or physical structure, such date cannot be effectively branded or marked on the cheese.

B.08.043. No manufacturer shell sell any cheese that is not made from a pasteurized source if it has been cut into smaller portions, unless

(a) it has been duly stored or
(b) each portion of cut cheese is marked, branded or labelled with the date of the beginning of the manufacturing process.

27-4-78 **B.08.044.** (1) Subject to subsection (2), no person shall sell cheese, including cheese curd, that is not made from a pasteurized source unless it has been stored.

18-10-79 (2) Cheese, including cheese curd, that is not made from a pasteurized source may be used as an ingredient in any food providing such food is manufactured or processed so as to pasteurize the cheese in the manner described in the definition "pasteurized source" in subsection B.08.030(1).

B.08.045. Notwithstanding B.08.044, cheese that has not been manufactured from a pasteurized source and has not been stored but is marked or branded with the date of the beginning of the manufacturing process, may be sold to

(a) a wholesaler;
(b) a jobber; or
(c) in quantities of not less than 900 pounds, to a retailer.

B.08.046. No person shall sell any whole cheese that has not been made from a pasteurized source unless there is stamped thereon the date of the beginning of the manufacturing process.

B.08.047. Every manufacturer, wholesaler, or jobber who sells cheese not made from a pasteurized source and which has not been stored shall keep a record of

(a) the registered number of the cheese factory;
(b) the date of manufacture of the cheese;
(c) the vat number or vat numbers;
(d) the name and address of the person to whom the cheese is sold; and
(e) the weight sold from each vat;

for each lot of cheese sold.

B.08.048. (1) Subject to section B.08.054, no person shall sell cheese, including cheese curd, made from a pasteurized source if the cheese contains more than

(a) 100 *Escherichia coli*, or
(b) 100 *Staphylococcus aureus*

per gram, as determined by official method MFO-14, Microbiological Examination of Cheese, November 30, 1983.

15-12-83 (2) No person shall sell cheese, made from an unpasteurized source if the cheese contains more than

(a) 500 *Escherichia coli*, or
(b) 1,000 *Staphylococcus aureus*

per gram, as determined by official method MFO-14, Microbiological Examination of Cheese, November 30, 1983.

B.08.049. [S]. Whey

(a) shall be the product remaining after the curd has been removed from milk in the process of making cheese; and

(b) may contain

(i) catalase, in the case of liquid whey that has been treated with hydrogen peroxide,

23-11-89 (ii) lactase,

(iii) hydrogen peroxide, in the case of liquid whey destined for the manufacture of dried whey products, and

(iv) benzoyl peroxide and calcium phosphate tribasic, as a carrier of the benzoyl peroxide, in the case of liquid whey destined for the manufacture of dried whey products other than those for use in infant formula.

13-6-95 **B.08.050. [S].** Revoked by P.C. 1995-922 of June 13, 1995.

B.08.051. [S]. Cottage Cheese

(a) shall be the product, in the form of discrete curd particles, prepared from skim milk, evaporated skim milk or skim milk powder and harmless acid-producing bacterial cultures;

(b) shall contain not more than 80 per cent moisture;

(c) may contain not more than 0.5 per cent stabilizing agent; and

2-4-92 (d) may contain

(i) milk,

(ii) cream,

(iii) milk powder,

(iv) rennet,

5-4-05 (v) milk coagulating enzymes derived from *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)), *Mucor pusillus Lindt* or *Aspergillus oryzae* RET-1 (pBoel777), in an amount consistent with good manufacturing practice,

2-4-92 (vi) Chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), in an amount consistent with good manufacturing practice,

4-4-95 (vi.1) Chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or *from Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), in an amount consistent with good manufacturing practice,

(vii) salt,

(viii) calcium chloride,

(ix) added lactose,

2-4-92 (x) pH adjusting agents,

(xi) relishes,

(xii) fruits,

(xiii) vegetables, and

1-3-01 (xiv) carbon dioxide.

B.08.052. [S]. **Creamed Cottage Cheese** shall be cottage cheese containing cream or a mixture of cream with milk or skim milk, or both, in such quantity that the final product shall contain

3-9-64 (a) not less than 4 per cent milk fat; and

(b) not more than 80 per cent moisture and may contain emulsifying, gelling, stabilizing and thickening agents.

9-3-61 **B.08.053.** All dairy products used in the preparation of cottage cheese shall be from a pasteurized source.

5-8-82 **B.08.054.** No person shall sell cottage cheese or creamed cottage cheese that contains more than 10 coliform bacteria per gram, as determined by official method MFO-4, Microbiological Examination of Cottage Cheese, November 30, 1981.

Butter

B.08.056. [S]. Butter

(a) shall

(i) be the food prepared in accordance with good manufacturing practices from milk or milk products, and

(ii) contain not less than 80 per cent milk fat; and

18-6-92 (b) may contain

(i) milk solids,

(ii) bacterial culture,

(iii) salt, and

(iv) food colour.

18-6-92 **B.08.057. [S]. Whey Butter** shall be butter made from whey cream.

Ice Cream

B.08.061. [S]. Ice Cream Mix

10-11-76 (a) shall be the unfrozen, pasteurized combination of cream, milk or other milk products, sweetened with sugar, liquid sugar, invert sugar, honey, dextrose, glucose, corn syrup, corn syrup solids of any combination of such sweeteners;

(b) may contain

(i) egg,

(ii) a flavouring preparation,

(iii) cocoa or chocolate syrup,

3-9-64 (iv) a food colour,

(v) pH adjusting agents,

18-12-75 (vi) microcrystalline cellulose or a stabilizing agent or both in an amount that will not exceed 0.5 per cent of the ice cream made from the mix,

(vii) a sequestering agent,

18-6-92 (viii) salt; and

(ix) not more than one per cent added edible casein or edible caseinates; and

(c) shall contain not less than

(i) 36 per cent solids, and

26-2-74 (ii) 10 per cent milk fat or, where cocoa or chocolate syrup has been added, 8 per cent milk fat.

B.08.062. [S]. Ice Cream

18-6-92 (a) shall be the frozen food obtained by freezing an ice cream mix, with or without the incorporation of air;

(b) may contain cocoa or chocolate syrup, fruit, nuts or confections;

(c) shall contain not less than

(i) 36 per cent solids,

26-2-74 (ii) 10 per cent milk fat or, where cocoa or chocolate syrup, fruit, nuts, or confections have been added, 8 per cent milk fat, and

18-6-92 (iii) 180 grams of solids per litre of which amount not less than 50 grams shall be milk fat, or, where cocoa or chocolate syrup, fruit, nuts or confections have been added, 180 grams of solids per litre of which amount not less than 40 grams shall be milk fat; and

(d) shall contain not more than

25-3-65 (i) 100,000 bacteria per gram, and

(ii) 10 coliform organisms per gram,

as determined by official method MFO-2, Microbiological Examination of Ice Cream or Ice Milk, November 30, 1981.

Sherbet

B.08.063. [S]. Sherbet

(a) shall be the frozen food, other than ice cream or ice milk, made from a milk product;
(b) may contain
(i) water,
3-9-64 (ii) a sweetening agent,
(iii) fruit or fruit juice,
(iv) citric or tartaric acid,
(v) a flavouring preparation,
(vi) a food colour,
(vii) not more than 0.75 per cent stabilizing agent,
(viii) a sequestering agent,
1-10-68 (ix) lactose,
(x) not more than 0.5 per cent microcrystalline cellulose; and
18-6-92 (xi) not more than one per cent added edible casein or edible caseinates; and
(c) shall contain
3-9-64 (i) not more than 5 per cent milk solids, including milk fat, and
(ii) not less than 0.35 per cent acid determined by titration and expressed as lactic acid.

Ice Milk

B.08.071. [S]. Ice Milk Mix

10-11-76 (a) shall be the unfrozen, pasteurized combination of cream, milk or other milk products, sweetened with sugar, liquid sugar, invert sugar, honey, dextrose, glucose, corn syrup, corn syrup solids or any combination of such sweeteners;
3-9-64 (b) may contain
(i) egg,
(ii) a flavouring preparation,
(iii) cocoa or chocolate syrup,
(iv) a food colour,
(v) a pH adjusting agent,
3-9-64 (vi) a stabilizing agent, in an amount that will not result in more than 0.5 per cent stabilizing agent in the ice milk,
(vii) a sequestering agent,
1-10-68 (viii) added lactose, and
(ix) not more than 1.5 per cent microcrystalline cellulose;
(x) salt; and
18-6-92 (xi) not more than one per cent added edible casein or edible caseinates; and
(c) shall contain
26-2-74 (i) not less than 33 per cent solids, and
(ii) not less than 3 per cent and not more than 5 per cent milk fat.

B.08.072. [S]. Ice Milk

18-6-92 (a) shall be the frozen food obtained by freezing an ice milk mix, with or without the incorporation of air;
(b) may contain cocoa or chocolate syrup, fruit, nuts or confections;
(c) shall contain
26-2-74 (i) not less than 33 per cent solids,
(ii) not less than 3 per cent and not more than 5 per cent milk fat, and
18-6-92 (iii) not less than 160 grams of solids per litre of which amount not less than 14 grams shall be milk fat; and
(d) shall contain not more than
2-3-65 (i) 100,000 bacteria per gram, and
(ii) 10 coliform organisms per gram,
5-8-82 as determined by official method MFO-2, Microbiological Examination of Ice Cream or Ice Milk, November 30, 1981.

29-10-92 **B.08.073.** Revoked by P.C. 1992-2261 of October 29, 1992.

31-10-88 **B.08.074.** (1) The percentage of milk fat contained in
(a) yogurt,
13-5-75 (b) cottage cheese, and
(c) creamed cottage cheese
shall be shown on the principal display panel followed by the words "milk fat" or the abbreviation "B.F." or "M.F.".

31-10-88 (2) In addition to the statement referred to in subsection (1), a person may, on the label of a food referred to in subsection (1), make a declaration of the fat content of the food, expressed in grams per serving of stated size.

Cream

B.08.075. [S]. Cream

23-11-67 (a) shall be the fatty liquid prepared from milk by separating the milk constituents in such a manner as to increase the milk fat content, and
(b) may contain
(i) a pH adjusting agent,
(ii) a stabilizing agent, and
(iii) in the case of cream for whipping that has been heat-treated above 100°C, the following ingredients and food additives:
(A) skim milk powder in an amount not exceeding 0.25 per cent,
11-8-88 (B) glucose solids in an amount not exceeding 0.1 per cent,
(C) calcium sulphate in an amount not exceeding 0.005 per cent,
(D) xanthan gum in an amount not exceeding 0.02 per cent, and
(E) microcrystalline cellulose in an amount not exceeding 0.2 per cent.

31-10-88 **B.08.076.** (1) The percentage of milk fat contained in canned cream shall be shown on the principal display panel followed by the words "milk fat" or the abbreviation "B.F." or "M.F.".
13-5-75

31-10-88 (2) In addition to the statement referred to in subsection (1), a person may, on the label of canned cream, make a declaration of the fat content of the cream, expressed in grams per serving of stated size.

B.08.077 [S]. Sour Cream

(a) shall be the product prepared by the souring of pasteurized cream with acid-producing bacterial culture and shall contain not less than 14 per cent milk fat; and

(b) may contain
(i) milk solids,
(ii) whey solids,
16-11-78 (iii) buttermilk,
(iv) starch in an amount not exceeding 1 per cent,
(v) salt,
(vi) rennet as a food enzyme in an amount consistent with good manufacturing practice,
26-6-80 (vii) the following emulsifying, gelling, stabilizing and thickening agents:
(A) algin, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, pectin or propylene glycol alginate or any combination thereof in an amount not exceeding 0.5 per cent,
(B) monoglycerides, mono and diglycerides, or any combination thereof, in an amount not exceeding 0.3 per cent, and
8-1-81 (C) sodium phosphate dibasic in an amount not exceeding 0.05 per cent,
(viii) sodium citrate as a flavour precursor in an amount not exceeding 0.1 per cent,
5-4-05 (ix) milk coagulating enzymes derived from *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)), *Mucor pusillus Lindt* or *Aspergillus oryzae* RET-1 (pBoel777), in an amount consistent with good manufacturing practice,
24-2-94 (x) Chymosin A derived from Escherichia coli K-12, GE81 (pPFZ87A), in an amount consistent with good manufacturing practice, and
4-4-95 (xi) Chymosin B derived from Aspergillus niger var. awamori, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), in an amount consistent with good manufacturing practice.

Fats and Oils

B.09.001. [S]. Vegetable fats and oils shall be fats and oils obtained entirely from the botanical source after which they are named, shall be dry and sweet in flavour and odour and, with the exception of olive oil, may contain emulsifying agents, Class IV preservatives, an antifoaming agent, and β-carotene in a quantity sufficient to replace that lost during processing, if such an addition is declared on the label.

14-2-85

B.09.002. [S]. Animal fats and oils shall be fats and oils obtained entirely from animals healthy at the time of slaughter, shall be dry and sweet in flavour and odour and may contain

(a) with the exception of milk fat and suet, Class IV preservatives; and
(b) with the exception of lard, milk fat and suet, an antifoaming agent.

17-11-77 **B.09.003. [S]. Olive Oil or Sweet Oil**

(a) shall be the oil obtained from the fruit of the olive tree (*Olea europaea L*);
(b) shall have a fatty acid content that is
  (i) not less than 56.0 and not more than 83.0 per cent oleic acid,
  (ii) not less than 7.5 and not more than 20.0 per cent palmitic acid,
  (iii) not less than 3.5 and not more than 20.0 per cent linoleic acid,
  (iv) not less than 0.5 and not more than 3.5 per cent stearic acid,
  (v) not less than 0.3 and not more than 3.5 per cent palmitoleic acid,
16-8-78 (vi) not more than 1.5 per cent linolenic acid, and
  (vii) not more than 0.05 per cent myristic acid, calculated as methyl esters;
(c) shall not contain more than minute amounts of arachidic acid, behenic acid, gadoleic acid or lignoceric acid;
(d) shall have
  (i) a relative density of not less than 0.910 and not more than 0.916, calculated with the oil at 20°C and water at 20°C (20°C/water at 20°C),
16-8-78 (ii) a refractive index of not less than 1.4677 and not more than 1.4705, calculated using the sodium D-line as the light source and with the oil at 20°C (n_D 20°C),
  (iii) an iodine value of not less than 75 and not more than 94, calculated using the Wijs test,
  (iv) a saponification value of not less than 184 and not more than 196, expressed as milligrams of potassium hydroxide per gram of oil,
  (v) an acid value of not more than 6.6 milligrams potassium hydroxide per gram of oil,
  (vi) a free acidity of not more than 3.3 per cent expressed as oleic acid,
  (vii) a peroxide value of not more than 20 milliequivalents peroxide oxygen per kilogram of oil,
  (viii) an unsaponifiable matter content of not more than 15 grams per kilogram, and
  (ix) a Bellier index of not more than 17;
(e) shall show negative results when tested for semi-siccative oil, olive-residue oil, cotton-seed oil, tea-seed oil or sesame seed oil; and
(f) notwithstanding section B.09.001, may contain alphatocopherol in a quantity sufficient to replace that lost during refining, if such an addition is declared on the label.

B.09.004. [S]. Cotton Seed Oil

(a) shall be the oil of the seeds of cultivated *Gossypium spp.*;
(b) shall have
  (i) a relative density (20°C/water at 20°C) of not less than 0.918 and not more than 0.926,
25-8-76 (ii) a refractive index (n_D 40°C) of not less than 1.458 and not more than 1.466,
  (iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 189 and not more than 198,
  (iv) an iodine value (Wijs) of not less than 99 and not more than 119,
  (v) an unsaponifiable matter content of not more than 15 grams per kilogram,
  (vi) a positive Halphen test,
  (vii) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and
  (viii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil; and
(c) may contain oxystearin.

20-5-97 **B.09.005. [S]. Cocoa Butter** shall be the fat from cocoa nibs, obtained either before or after roasting, or cocoa liquor, and shall have

3-9-64 (a) a refractive index (40°C) of not less than 1.453 and not more than 1.458;
(b) a saponification value of not less than 188 and not more than 202;
(c) an iodine value (Hanus) of not less than 32 and not more than 41; and
(d) an acid value of not more than 5.

28-5-76 **B.09.006. [S]. Corn Oil** or **Maize Oil**

* (a) shall be the oil of the germ or embryo of *Zea mays L*; and
(b) shall have
(i) a relative density (20°C/water at 20°C) of not less than 0.917 and not more than 0.925,
(ii) a refractive index (n_D 40°C) of not less than 1.465 and not more than 1.468,
(iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 187 and not more than 195,
(iv) an iodine value (Wijs) of not less than 103 and not more than 128,
(v) an unsaponifiable matter content of not more than 28 grams per kilogram,
(vi) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and
(vii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil.

B.09.007. [S]. Peanut Oil or **Arachis Oil**

(a) shall be oil of the seeds of *Arachis hypogaea L*;
25-8-76 (b) shall have
(i) a relative density (20°C/water at 20°C) of not less than 0.914 and not more than 0.917,
(ii) a refractive index (n_D 40°C) of not less than 1.460 and not more than 1.465,
(iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 187 and not more than 196,
(iv) an iodine value (Wijs) of not less than 80 and not more than 106,
(v) an unsaponifiable matter content of not more than 10 grams per kilogram,
(vi) an arachidic and higher fatty acids content of not less than 48 grams per kilogram,
(vii) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and
(viii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil; and

(c) may contain oxystearin.

B.09.008. [S]. Soybean Oil, Soya Bean Oil, Soja Oil or **Soya Oil**

(a) shall be the oil of the seeds of *Glycine max (L.) Merr.*;
(b) shall have
(i) a relative density (20°C/water at 20°C) of not less than 0.919 and not more than 0.925,
(ii) a refractive index (n_D 40°C) of not less than 1.466 and not more than 1.470,
25-8-76 (iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 189 and not more than 195,
(iv) an iodine value (Wijs) of not less than 120 and not more than 143,
(v) an unsaponifiable matter content of not more than 15 grams per kilogram,
(vi) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and
(vii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil; and

(c) may contain oxystearin.

B.09.009. [S]. Sunflowerseed Oil or **Sunflower Oil**

(a) shall be the oil of the seeds of *Helianthus annuus L.*; and
(b) shall have
(i) a relative density (20°C/water at 20°C) of not less than 0.918 and not more than 0.923,
25-8-76 (ii) a refractive index (n_D 40°C) of not less than 1.467 and not more than 1.469,
(iii) an iodine value (Wijs) of not less than 110 and not more than 143,
(iv) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 188 and not more than 194,
(v) an unsaponifiable matter content of not more than 15 grams per kilogram,
(vi) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and
(vii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil.

B.09.009A. [S]. Safflowerseed Oil or **Safflower Oil**

(a) shall be the oil of the seeds of *Carthamus tinctorius L.*;
(b) shall have
(i) a relative density (20°C/water at 20°C) of not less than 0.922 and not more than 0.927,
(ii) a refractive index (n_D 40°C) of not less than 1.467 and not more than 1.470,
25-8-76 (iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 186 and not more than 198,
(iv) an iodine value (Wijs) of not less than 135 and not more than 150,
(v) an unsaponifiable matter content of not more than 15 grams per kilogram,
(vi) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and
(vii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil.

13-5-75 **B.09.010.** Notwithstanding item 1 of the table to paragraph B.01.010(3)(b) where a vegetable fat or oil is an ingredient of any cooking oil, salad oil or table oil, the fat or oil shall be shown in the list of ingredients by its common name.

B.09.011. [S]. **Shortening**, other than butter or lard, shall be the semi-solid food prepared from fats, oils or a combination of fats and oils, may be processed by hydrogenation and may contain

(a) Class IV preservatives;
(b) an antifoaming agent;
3-9-64 (c) stearyl monoglyceridyl citrate;
(d) monoglycerides or a combination of monoglycerides and diglycerides of fat forming fatty acids, the weight of the monoglycerides being not more than 10 per cent and the total weight of monoglycerides and diglycerides being not more than 20 per cent of the weight of the shortening;
(e) lactylated monoglycerides, or a combination of lactylated monoglycerides and diglycerides of fat forming fatty acids, the total weight being not more than 8 per cent of the weight of the shortening; and
(f) sorbitan tristearate

18-12-75 except that the total weight of the ingredients permitted under paragraphs (d) and (e) shall not be greater than 20 per cent of the weight of the shortening.

19-3-97 **B.09.012. [S].** Repealed by P.C. 1997-378 of March 19, 1997.

B.09.013. [S]. **Lard.**

(a) shall be the rendered fat from hogs;
(b) shall have
(i) a relative density of not less than 0.894 and not more than 0.906, calculated with the lard at 40°C and water at 20°C (40°C/water at 20°C),
(ii) a refractive index of not less than 1.448 and not more than 1.461, calculated using the sodium D-line as the light source and with the lard at 40°C (n_D 40°C),
(iii) a titre of not less than 32°C and not more than 45°C,
(iv) a saponification value of not less than 192 and not more than 203, expressed as milligrams potassium hydroxide per gram of fat,
17-11-77 (v) an iodine value of not less than 45 and not more than 70, calculated using the Wijs test,
(vi) an unsaponifiable matter content of not more than 12 grams per kilogram,
(vii) an acid value of not more than 2.5 milligrams potassium hydroxide per gram of fat, and
(viii) a peroxide value of not more than 16 milliequivalents peroxide oxygen per kilogram of fat; and

(c) may contain
(i) lard stearine or hydrogenated lard,
(ii) a Class IV preservative, and
(iii) not more than one per cent of substances resulting from the rendering process, other than fatty acids and fat.

3-9-64 **B.09.014. [S].** **Leaf Lard** shall be lard that has been rendered at a moderately high temperature from the internal fat of the abdomen of the hog, excluding that adhering to the intestines, and shall have an iodine value (Hanus) of not more than 65.

B.09.015. [S]. **Suet.**

(a) shall be the fat taken from the region of the kidney or loin or caul fat of a beef carcass;
(b) shall have
(i) a relative density of not less than 0.893 and not more than 0.898, calculated with the suet at 40°C and water at 20°C (40°C/water at 20°C),
17-11-77 (ii) a refractive index of not more than 1.448 and not more than 1.460, calculated using the sodium D-line as the light source and with the suet at 40°C (n_D 40°C),
(iii) a titre of not less than 42.5°C and not more than 47°C,
(iv) a saponification value of not less than 190 and not more than 200, expressed as milligrams of potassium hydroxide per gram of fat,
(v) an iodine value of not less than 32 and not more than 47, calculated using the Wijs test,

(vi) an unsaponifiable matter content of not more than 10 grams per kilogram,
(vii) an acid value of not more than 2.0 milligrams potassium hydroxide per gram of fat, and
(viii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of fat; and

(c) where sold in comminuted form, shall contain not more than three per cent cereal and one per cent salt.

B.09.016. [S]. Margarine

17-11-77 (a) shall be a plastic or fluid emulsion of water in fats, oil or fats and oil that are not derived from milk and may have been subjected to hydrogenation;
(b) shall contain
(i) not less than 80 per cent fat, oil or fat and oil calculated as fat, and
(ii) notwithstanding section D.01.009, not less than
(A) 3300 International Units of vitamin A, and
(B) 530 International Units of vitamin D per 100 grams; and

(c) may contain
(i) skim milk powder, buttermilk powder or liquid buttermilk,
(ii) whey solids or modified whey solids,
(iii) protein,
(iv) water,
(v) vitamin E, if added in such an amount as will result in the finished product containing not less than 0.6 International Unit of alphatocopherol per gram of linoleic acid present in the margarine,
(vi) a flavouring agent,
(vii) a sweetening agent,
(viii) potassium chloride and sodium chloride,
23-9-93 (ix) the following colouring agents: annatto, β-apo-8'-carotenal, canthaxanthin, carotene, ethyl β-apo-8'-carotenoate and turmeric, as set out in Table III to section B.16.100,
(x) the following emulsifying agents: lecithin, mono- and di-glycerides, mono-glycerides and sorbitan tristearate, as set out in Table IV to section B.16.100,
(xi) the following pH adjusting agents: citric acid, lactic acid, potassium bicarbonate, sodium bicarbonate, potassium carbonate, sodium carbonate, sodium citrate, sodium lactate, potassium citrate, potassium hydroxide, sodium hydroxide, potassium lactate, sodium potassium tartrate and tartaric acid, as set out in Table X to section B.16.100,
(xii) the following preservatives: ascorbyl palmitate, ascorbyl stearate, benzoic acid, butylated hydroxyanisole, butylated, hydroxytoluene, calcium sorbate, monoglyceride citrate, monoisopropyl citrate, potassium benzoate, potassium sorbate, propyl gallate, sodium benzoate, sodium sorbate and sorbic acid, as set out in Table XI to section B.16.100, and
(xiii) the following sequestering agents: calcium disodium ethylenediaminetetraacetate and stearyl citrate, as set out in Table XII to section B.16.100.

B.09.017. [S]. Calorie-Reduced Margarine

17-11-77 (a) shall conform to the standard for margarine except it shall contain not more than
(i) 40 per cent fat, oil or fat and oil calculated as fat, and
(ii) 50 per cent of the calories that would be normally present in the product if it were not calorie-reduced;

(b) subject to paragraph (c), may contain, either singly or in combination, in an amount not exceeding 0.5 per cent,
(i) acacia gum,
(ii) agar,
(iii) algin,
(iv) carob bean gum,
19-3-96 (v) carrageenan,
(vi) furcelleran,
(vii) gellan gum,
(viii) guar gum,
(ix) karaya gum,
(x) propylene glycol alginate,
(xi) tragacanth gum, and
(xii) xanthan gum;

*(R) Minor correction

(c) may
  (i) if it contains none of the ingredients mentioned in paragraph (b), contain polyglycerol esters of fatty acids in an amount not exceeding 0.2 per cent, or

19-3-96

  (ii) if it contains a combination of one or more of the ingredients mentioned in paragraph (b) and polyglycerol esters of fatty acids, contain such esters in an amount not exceeding 0.2 per cent, provided that the total combination of such esters and ingredients does not exceed an amount of 0.5 per cent;

(d) notwithstanding subparagraph B.09.016(c)(x), may contain lecithin in an amount not exceeding 0.5 per cent; and

(e) may contain
  (i) vegetable starch,
  (ii) modified vegetable starch, and
  (iii) maltodextrin.

31-10-88

B.09.020. Revoked by P.C. 1988-2457 of October 31, 1988.

B.09.021. Revoked by P.C. 1988-2457 of October 31, 1988.

13-5-75

B.09.022. No person shall sell cooking oil, margarine, salad oil, simulated dairy product, shortening or food that resembles margarine or shortening, if the product contains more than 5 per cent C_{22} Monoenoic Fatty Acids calculated as a proportion of the total fatty acids contained in the product.

Flavouring Preparations

B.10.003. [S]. **(naming the flavour) Extract** or **(naming the flavour) Essence** shall be a solution in ethyl alcohol, glycerol, propylene glycol or any combination of these, of sapid or odorous principles, or both, derived from the plant after which the flavouring extract or essence is named, and may contain water, a sweetening agent, food colour and a Class II preservative or Class IV preservative.

3-9-64

B.10.004. [S]. **Artificial (naming the flavour) Extract, Artificial (naming the flavour) Essence, Imitation (naming the flavour) Extract** or **Imitation (naming the flavour) Essence** shall be a flavouring extract or essence except that the flavouring principles shall be derived in whole, or in part, from sources other than the aromatic plant after which it is named, and if such extract or essence is defined in these Regulations, the flavouring strength of the artificial or imitation extract or essence shall be not less than that of the extract or essence.

B.10.005. [S]. **(naming the flavour) Flavour**

(a) shall be a preparation, other than a flavouring preparation described in section B.10.003, of sapid or odorous principles, or both, derived from the aromatic plant after which the flavour is named;

4-12-86 (b) may contain a sweetening agent, food colour, Class II preservative, thaumatin, Class IV preservative or emulsifying agent; and

23-1-75 (c) may have added to it the following liquids only:

(i) water;

(ii) any of, or any combination of, the following: benzyl alcohol; 1,3-butylene glycol, ethyl acetate, ethyl alcohol, glycerol, glyceryl diacetate, glyceryl triacetate, glyceryl tributyrate, isopropyl alcohol, monoglycerides and diglycerides; 1,2-propylene glycol or triethylcitrate;

(iii) edible vegetable oil; and

28-4-77 (iv) brominated vegetable oil, sucrose acetate isobutyrate or mixtures thereof, when such flavour is used in citrus-flavoured or spruce-flavoured beverages.

B.10.006. [S]. **Artificial (naming the flavour) Flavour** or **Imitation (naming the flavour) Flavour** shall be a flavour except that the flavouring principles may be derived in whole or in part from sources other than the aromatic plant after which it is named, and if such flavour is defined in these Regulations, the flavouring strength of the artificial or imitation flavour shall be not less than that of the flavour.

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B.10.007. [S]. Notwithstanding sections B.10.003 and B.10.005, a **(naming the fruit) Extract Naturally Fortified, (naming the fruit) Essence Naturally Fortified** or **(naming the fruit) Flavour Naturally Fortified** shall be an extract, essence or flavour derived from the named fruit to which other natural extractives have been added and 51 per cent of the flavouring strength shall be derived from the named fruit.

12-4-84 **B.10.008.** On any label of or in any advertisement for an artificial or imitation flavouring preparation, the word "artificial" or "imitation" shall be an integral part of the name of such flavouring preparation and shall be set out in identical type and be identically displayed with such name.

B.10.009. [S]. **Almond Essence, Almond Extract** or **Almond Flavour** shall be the essence, extract or flavour derived from the kernels of the bitter almond, apricot or peach and shall contain not less than 1 per cent by volume of hydrocyanic acid-free volatile oil obtained therefrom.

3-9-64 **B.10.010. [S].** **Anise Essence, Anise Extract** or **Anise Flavour** shall be the essence, extract or flavour derived from natural or terpeneless oil of anise and shall correspond in flavouring strength to an alcoholic solution containing not less than 3 per cent by volume of oil of anise, the volatile oil obtained from the fruit of *Pimpinella anisum L.* or *Illicium verum* Hook.

B.10.011. [S]. **Celery Seed Essence, Celery Seed Extract** or **Celery Seed Flavour** shall be the essence, extract or flavour derived from celery seed, or oil of celery seed, or terpeneless oil of celery seed and shall correspond in flavouring strength to an alcoholic solution containing not less than 0.3 per cent by volume of volatile oil of celery seed.

B.10.012. [S]. **Cassia Essence, Cassia Extract, Cassia Cinnamon Essence, Cassia Cinnamon Extract, Cassia Flavour** or **Cassia Cinnamon Flavour** shall be the essence, extract or flavour derived from natural or terpeneless oil, obtained from leaves and twigs of *Cinnamomum cassia L.* containing not less than 80 per cent cinnamic aldehyde, and shall correspond in flavouring strength to an alcoholic solution containing not less than 2 per cent by volume of volatile oil of cassia cinnamon.

B.10.013. [S]. **Ceylon Cinnamon Essence, Ceylon Cinnamon Extract** or **Ceylon Cinnamon Flavour** shall be the essence, extract or flavour derived from the volatile oil obtained from the bark of *Cinnamomum zeylanisum* Nees, and shall contain

(a) not less than 2 per cent by volume of oil of Ceylon cinnamon;
(b) not less than 65 per cent cinnamic aldehyde; and
(c) not more than 10 per cent eugenol.

B.10.014. [S]. **Clove Essence, Clove Extract** or **Clove Flavour** shall be the essence, extract or flavour derived from the volatile oil obtained from clove buds, and shall contain not less than 2 per cent by volume of oil of clove.

B.10.015. [S]. **Ginger Essence, Ginger Extract** or **Ginger Flavour** shall be the essence, extract or flavour derived from ginger and shall contain in 100 millilitres the alcohol-soluble matter from not less than 20 grams of ginger.

B.10.016. [S]. **Lemon Essence, Lemon Extract** or **Lemon Flavour** shall be the essence, extract or flavour prepared from natural or terpeneless oil of lemon or from lemon peel and shall contain not less than 0.2 per cent citral derived from oil of lemon.

3-9-64 **B.10.017. [S].** **Nutmeg Essence, Nutmeg Extract** or **Nutmeg Flavour** shall be the essence, extract or flavour prepared from natural or terpeneless oil of nutmeg and shall correspond in flavouring strength to an alcoholic solution containing not less than 2 per cent by volume of oil of nutmeg.

B.10.018. [S]. **Orange Essence, Orange Extract** or **Orange Flavour** shall be the essence, extract or flavour prepared from sweet orange peel, oil of sweet orange or terpeneless oil of sweet orange, and shall correspond in flavouring strength to an alcoholic solution containing 5 per cent by volume of oil of sweet orange, the volatile oil obtained from the fresh peel of *Citrus aurantium L.*, that shall have an optical rotation, at a temperature of 25°C, of not less than +95° using a tube 100 millimetres in length.

B.10.019. [S]. **Peppermint Essence, Peppermint Extract** or **Peppermint Flavour** shall be the essence, extract or flavour prepared from peppermint or oil of peppermint, obtained from the leaves and flowering tops of *Mentha piperita L.*, or of *Mentha arvensis* De.C., var. *piperascens* Holmes, and shall correspond in flavouring strength to an alcoholic solution of not less than 3 per cent by volume of oil of peppermint, containing not less than 50 per cent free and combined menthol.

B.10.020. [S]. **Rose Essence, Rose Extract** or **Rose Flavour** shall be the essence, extract or flavour prepared from the volatile oil obtained from the petals of *Rosa damascena* Mill., *R. centajolia L.*, or *R. moschata* Herrm, and shall contain not less than 0.4 per cent by volume of attar of rose.

B.10.021. [S]. **Savory Essence, Savory Extract** or **Savory Flavour** shall be the essence, extract or flavour prepared from savory or oil of savory and shall contain not less than 0.35 per cent by volume of oil of savory.

B.10.022. [S]. **Spearmint Essence, Spearmint Extract** or **Spearmint Flavour** shall be the essence, extract or flavour prepared from spearmint or from oil of spearmint, obtained from the leaves and flowering tops of *Mentha spicata L.* and shall contain not less than 3 per cent by volume of oil of spearmint.

B.10.023. [S]. **Sweet Basil Essence, Sweet Basil Extract** or **Sweet Basil Flavour** shall be the essence, extract or flavour prepared from sweet basil or from oil of sweet basil, obtained from the leaves and tops of *Ocymum basilicum L.* and shall contain not less than 0.1 per cent by volume of oil of sweet basil.

B.10.024. [S]. **Sweet Marjoram Essence, Sweet Marjoram Extract, Marjoram Essence, Marjoram Extract, Sweet Marjoram Flavour** or **Marjoram Flavour** shall be the essence, extract or flavour prepared from marjoram or from oil of marjoram and shall contain not less than 1 per cent by volume of oil of marjoram.

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B.10.025. [S]. **Thyme Essence, Thyme Extract** or **Thyme Flavour** shall be the essence, extract or flavour prepared from thyme or from oil of thyme and shall contain not less than 0.2 per cent by volume of oil of thyme.

B.10.026. [S]. **Vanilla Extract, Vanilla Essence** or **Vanilla Flavour**

(a) shall be the essence, extract or flavour prepared from the vanilla bean, the dried, cured fruit of *Vanilla planifolia*, Andrews, or *Vanilla tahitensia*, J.W. Moore;

(b) shall contain in 100 ml, regardless of the method of extraction, at least the quantity of soluble substances in their natural proportions that are extractable, according to official method FO-17, *Extraction of Soluble Substances from Vanilla Beans*, dated September 15, 1989, from

14-2-91

(i) not less than 10 g of vanilla beans, where the beans contain 25 per cent or less moisture, and

(ii) not less than 7.5 g of vanilla beans on the moisture-free basis, where the beans contain more than 25 per cent moisture; and

(c) notwithstanding sections B.10.003 and B.10.005, shall not contain added colour.

3-9-64

B.10.027. [S]. **Wintergreen Essence, Wintergreen Extract** or **Wintergreen Flavour** shall be the essence, extract or flavour prepared from oil of wintergreen, the volatile oil distilled from the leaves of *Gaultheria procumbens L.* or from *Betula lenta L.* and shall contain not less than 3 per cent by volume of oil of wintergreen.

Fruits, Vegetables, their Products and Substitutes

B.11.001. In this DIVISION

3-9-64 (a) an acid ingredient means
- (i) citric, malic or tartaric acid,
- (ii) lemon or lime juice, or
- (iii) vinegar;

28-4-77 (b) a sweetening ingredient means sugar, invert sugar, honey, dextrose, glucose or glucose solids or any combination thereof in dry or liquid form; and

15-6-67 (c) fruit juice means the unfermented liquid expressed from sound ripe fresh fruit, and includes any such liquid that is heat treated and chilled.

25-6-87 **B.11.001.1.** No person shall sell any fresh fruit or vegetable that is intended to be consumed raw, except grapes, if sulphurous acid or any salt thereof has been added thereto.

Vegetables

12-4-84 **B.11.002. [S].** Canned **(naming the vegetable)**

13-5-75 (a) shall be the product obtained by heat processing the named fresh vegetable after it has been properly prepared;

(b) shall be packed in hermetically sealed containers;

(c) may contain
- (i) a sweetening ingredient,

28-4-77
- (ii) salt,
- (iii) water, and
- (iv) a firming agent; and

(d) may contain
- (i) in the case of canned green beans and canned wax beans, pieces of green peppers, red peppers and tomato in an amount not exceeding 15 per cent of the final product, and dill seasonings and vinegar,
- (ii) in the case of canned peas, garnishes composed of one or more of lettuce, onions, carrots, and pieces of green or red peppers in an amount not exceeding 15 per cent of the total drained vegetable ingredient, aromatic herbs, spices and seasonings, stock or juice of vegetables and aromatic herbs, calcium hydroxide in an amount not exceeding 0.01 per cent of the final product and magnesium hydroxide in an amount not exceeding 0.05 per cent of the final product,
- (iii) in the case of
  - (A) canned asparagus, acetic acid, citric acid, malic acid and tartaric acid at levels consistent with good manufacturing practice,
  - (B) canned white asparagus, acetic acid, citric acid, malic acid, tartaric acid and ascorbic acid at levels consistent with good manufacturing practice; and

9-12-97
  - (C) canned chili peppers, citric acid at a level consistent with good manufacturing pratice,

13-9-79
- (iv) in the case of asparagus packed in glass containers or fully lined (lacquered) cans, stannous chloride in an amount not exceeding 25 parts per million, calculated as tin,
- (v) in the case of canned artichokes, canned bean sprouts and canned onions, citric acid at levels consistent with good manufacturing practice, to be used as a pH adjusting agent,
- (vi) in the case of canned ripe lima beans (butter beans) and canned pinto beans, calcium disodium ethylenediaminetetraacetate in an amount not exceeding 130 parts per million,

30-8-95
- (vi.1) in the case of canned fava beans, calcium disodium ethylenediaminetetraacetate in an amount not exceeding 365 parts per million,
- (vii) in the case of canned red kidney beans, canned chick peas (garbanzo beans) and canned black-eye peas, disodium ethylenediaminetetraacetate in an amount not exceeding 150 parts per million, and
- (viii) in the case of canned asparagus, canned green beans, canned wax beans and canned peas
  - (A) butter or other edible animal or vegetable fats or oils, but if butter is added it shall be not less than 3 per cent of the final product,
  - (B) natural or enzymatically or physically modified starches when used with butter or other edible animal or vegetable fats and oils,
  - (C) acacia gum, algin, carrageenan, furcelleran, guar gum and propylene glycol alginate used with butter or other edible animal or vegetable fats or oils in an amount not exceeding 1 per cent, singly or in any combination, of the final product, and
  - (D) characterizing sauces, seasonings or flavouring agents if it is included in the common name of the product.

*(R) Minor correction

12-4-84 **B.11.003. [S].** Canned **Mushrooms**

9-9-70 (a) shall be the product obtained by heat processing properly prepared mushrooms of the cultivated type;

(b) shall be packed in hermetically sealed containers; and

27-3-73 (c) may contain ascorbic acid, citric acid and salt.

B.11.003A. [S]. Frozen Mushrooms

9-9-70 (a) shall be the product obtained by freezing properly prepared mushrooms of the cultivated type; and

13-5-75 (b) may contain sodium metabisulphite, sodium phosphate dibasic, sodium sulphate and salt.

13-5-75 **B.11.004. [S].** Frozen (naming the vegetable) shall be the product obtained by freezing the named fresh vegetable after it has been properly prepared and subjected to a blanching treatment and may contain added salt.

B.11.005. [S]. Tomatoes or Canned Tomatoes

6-6-74 (a) shall be the product made by heat processing properly prepared fresh ripe tomatoes;

(b) may contain

24-6-75 (i) a sweetening ingredient in dry form,

(ii) salt,

(iii) a firming agent,

(iv) citric acid, and

(v) spice or other seasoning; and

5-8-82 (c) shall contain not less than 50 per cent drained tomato solids, as determined by official method FO-18, Determination of Drained Tomato Solids, October 15, 1981.

24-6-75 **B.11.007. [S]. Tomato Juice** shall be the unconcentrated, pasteurized liquid containing a substantial portion of fine tomato pulp extracted from sound, ripe, whole tomatoes from which all stems and objectionable portions have been removed by any method that does not add water to the liquid and may contain salt and a sweetening ingredient in dry form.

B.11.009. [S]. Tomato Paste shall be the product made by evaporating a portion of the water from tomatoes or sound tomato trimmings, may contain salt and Class II preservatives and shall contain not less than 20 per cent tomato solids, as determined by official method FO-19, Determination of Tomato Solids, October 15, 1981.

5-8-82

B.11.010. [S]. Concentrated Tomato Paste shall be tomato paste containing not less than 30 per cent tomato solids, as determined by official method FO-19, Determination of Tomato Solids, October 15, 1981.

3-9-64 **B.11.011. [S]. Tomato Pulp** shall be the heat processed product made from whole, ripe tomatoes or sound tomato trimmings concentrated to yield a product with a specific gravity of not less than 1.050 (20°C/20°C) and may contain salt and a Class II preservative.

3-9-64 **B.11.012. [S]. Tomato Puree** shall be the heat processed product made from whole, ripe tomatoes, with the skins and seeds removed, concentrated to yield a product with a specific gravity of not less than 1.050 (20°C/20°C) and may contain salt and a Class II preservative.

B.11.014. [S]. Tomato Catsup, Catsup or products whose common names are variants of the word Catsup

(a) shall be the heat processed product made from the juice of red-ripe tomatoes or sound tomato trimmings from which skins and seeds have been removed;

3-9-64 (b) shall contain

(i) vinegar,

(ii) salt,

(iii) seasoning, and

24-6-75 (iv) a sweetening ingredient; and

3-9-64 (c) may contain

(i) a Class II preservative, and

(ii) food colour.

19-3-97 **B.11.015.** Repealed by P.C. 1997-381 of March 19, 1997.

5-8-82 **B.11.016.** No person shall sell canned tomatoes, tomato juice or vegetable juice that contains mould filaments in more than 25 per cent of the microscopic fields, when examined by official method MFO-5, Examination of Canned Tomatoes, Tomato Juice and Vegetable Juice, Tomato Puree, Tomato Paste, Tomato Pulp and Tomato Catsup for Mould Filaments, November 30, 1981.

5-8-82 **B.11.017.** No person shall sell tomato puree, tomato paste, tomato pulp or tomato catsup that contains mould filaments in more than 50 per cent of the microscopic fields, when examined by official method MFO-5, Examination of Canned Tomatoes, Tomato Juice and Vegetable Juice, Tomato Puree, Tomato Paste, Tomato Pulp and Tomato Catsup for Mould Filaments, November 30, 1981.

3-9-64 **B.11.025.** No person shall sell potatoes, sweet potatoes or yams that have been artificially coloured.

B.11.040. [S]. **Beans with Pork** or **Beans and Pork** shall be the food prepared from dried beans and pork, may contain sauce, seasoning, spices and a sweetening agent and shall contain not less than 60 per cent drained solids, as determined by official method FO-20, Determination of Drained Solids of Beans with Pork or Beans and Pork and Beans or Vegetarian Beans, October 15, 1981.

5-8-82

B.11.041. [S]. **Beans** or **Vegetarian Beans** shall be the food prepared from dried beans, may contain sauce, seasoning, spices and a sweetening agent and shall contain not less than 60 per cent drained solids, as determined by official method FO-20, Determination of Drained Solids of Beans with Pork or Beans and Pork and Beans or Vegetarian Beans, October 15, 1981.

B.11.050. [S]. Olives shall be the plain or stuffed fruit of the olive tree, and may contain

(a) vinegar;
24-6-75 (b) salt;
3-9-64 (c) a sweetening ingredient;
(d) spices;
(e) seasonings;
(f) lactic acid; and
(g) sorbic acid or its potassium or sodium salt;
(h) calcium chloride;
9-12-97 (i) citric acid; and
(j) in the case of ripe olives, ferrous gluconate.

12-4-84 **B.11.051. [S].** Pickles and relishes shall be the product prepared from vegetables or fruits with salt and vinegar, and may contain

(a) spices;
(b) seasonings;
(c) sugar, invert sugar, dextrose or glucose, in dry or liquid form;
3-9-64 (d) food colour;
(e) a Class II preservative;
(f) a firming agent;
(g) polyoxyethylene (20) sorbitan monooleate in an amount not exceeding 0.05 per cent;
(h) lactic acid;
15-6-67 (i) vegetable oils; and
(j) in the case of relishes and mustard pickles, a thickening agent.

Fruits

12-4-84 **B.11.101. [S].** Canned **(naming the fruit)**

(a) shall be the product prepared by heat processing the named fresh fruit after it has been properly prepared;
3-9-64 (b) shall be packed in hermetically sealed containers; and
(c) may contain
(i) a sweetening ingredient,
(ii) water,
(iii) fruit juice, fruit juice from concentrate, concentrated fruit juice or any combination thereof,
(iv) in the case of canned pears, citric acid, malic acid, L-tartaric or lactic acid at a level sufficient to maintain pH 4.2 to 4.5, lemon juice, spices, spice oils, mint and a flavouring preparation other than that which simulates the flavour of canned pears,
(v) in the case of canned apples, a firming agent,
(vi) in the case of canned applesauce, citric acid and malic acid at a level sufficient to maintain pH 4.2 to 4.5, ascorbic acid and isoascorbic acid provided the total does not exceed 150 parts per million, spices, salt and a flavouring preparation other than that which simulates the flavour of canned applesauce,
17-11-77 (vii) in the case of canned grapefruit, citric acid at a level sufficient to maintain pH 4.2 to 4.5, lemon juice, calcium chloride and calcium lactate provided the total calcium content, whether naturally present or added, does not exceed 0.035 per cent, spices and a flavouring preparation other than that which simulates the flavour of canned grapefruit,
(viii) in the case of canned mandarin oranges, citric acid at a level sufficient to maintain pH 4.2 to 4.5,
(ix) in the case of canned peaches, L-ascorbic acid at a level not to exceed 550 parts per million, spices, peach pits and peach kernels intended for flavour development and a flavouring preparation other than that which simulates the flavour of canned peaches,
(x) in the case of canned pineapple, citric acid at a level sufficient to maintain pH 4.2 to 4.5, spices, spice oils, mint, dimethylpolysiloxane not to exceed 10 parts per million when pineapple juice is used as a packing medium and a flavouring preparation other than that which simulates the flavour of canned pineapple,
(xi) in the case of canned plums, a flavouring preparation other than that which simulates the flavour of canned plums, and
(xii) in the case of canned strawberries, citric acid, lactic acid, malic acid or L-tartaric acid at a level sufficient to maintain pH 4.2 to 4.5.

12-4-84 **B.11.102. [S].** Frozen **(naming the fruit)** shall be the product obtained by freezing the named fresh fruit after it has been properly prepared and may contain

(a) a sweetening ingredient;
28-4-77 (b) water;
(c) fruit juice, fruit juice from concentrate, concentrated fruit juice or any combination thereof;
30-8-95 (d) ascorbic acid, citric acid, erythorbic acid or malic acid to prevent discolouration; and
(e) in the case of frozen sliced apples,
(i) a firming agent, and
(ii) sulphurous acid.

B.11.103. Revoked by P.C. 1979-675 of March 8, 1979.

B.11.104. Revoked by P.C. 1979-675 of March 8, 1979.

19-3-97 **B.11.105.** Repealed by P.C. 1997-381 of March 19, 1997.

*(R) Minor correction

B.11.120. [S]. (Naming the fruit) Juice

5-10-92

(a) shall be the juice obtained from the named fruit; and
(b) may contain a sweetening ingredient in dry form, a Class II preservative, amylase, cellulase and pectinase.

28-6-68 **B.11.121.** Notwithstanding section B.11.120, the fruit juice prepared from any fruit named in any of sections B.11.123 to B.11.128A shall conform to the standard prescribed for that fruit juice in that section.

B.11.123. [S]. Apple Juice

(a) shall be the fruit juice obtained from apples;
18-1-90 (b) may contain a Class II preservative, vitamin C, amylase, cellulase and pectinase;
(c) shall have a specific gravity of not less than 1.041 and not more than 1.065 (20°C/20°C); and
3-9-64 (d) shall contain, in 100 millilitres measured at a temperature of 20°C, not less than 0.24 gram and not more than 0.60 gram of ash of which not less than 50 per cent shall be potassium carbonate.

B.11.124. [S]. Grape Juice

30-4-74 (a) shall be the fruit juice obtained from grapes;
(b) shall have a specific gravity of not less than 1.040 and not more than 1.124 (20°C/20°C);
(c) shall contain, before the addition of a sweetening ingredient, in 100 millilitres measured at a temperature of 20°C,
24-6-75 (i) not less than 0.20 gram and not more than 0.55 gram of ash, and
(ii) not less than 0.015 gram and not more than 0.070 gram of phosphoric acid calculated as phosphorous pentoxide; and

18-1-90 (d) may contain a pH-adjusting agent, a sweetening ingredient in dry form, a Class II preservative, vitamin C, amylase, cellulase and pectinase.

B.11.125. [S]. Grapefruit Juice

30-4-74 (a) shall be fruit juice obtained from clean, sound, mature grapefruit;
(b) shall
(i) contain not less than 1.15 milliequivalents of free amino acid per 100 millilitres, as determined by official method FO-21, Determination of Amino Acids in Grapefruit Juice and Orange Juice, October 15, 1981,
(ii) contain not less than 70 milligrams of potassium per 100 millilitres, as determined by official method FO-22, Determination of Potassium in Grapefruit and Orange Juice, October 15, 1981, and
(iii) have an absorbance value for total polyphenolics of not less than 0.310, as determined by official method FO-23, Determination of Absorbance Value for Total Polyphenolics in Grapefruit Juice and Orange Juice, October 15, 1981;

5-8-82 (c) shall, before the addition of sugar, invert sugar, dextrose or glucose solids,
(i) have a Brix reading of not less than 9.3°, as determined by official method FO-24, Determination of Brix Reading for Grapefruit Juice and Orange Juice, October 15, 1981, and
(ii) contain not less than 0.7 per cent and not more than 2.1 per cent of acid by weight calculated as anhydrous citric acid, as determined by official method FO-25, Determination of Acid in Grapefruit Juice or Orange Juice, October 15, 1981; and

18-1-90 (d) may contain sugar, invert sugar, dextrose in dry form, glucose solids, a Class II preservative, amylase, cellulase and pectinase.

*(R) Minor correction

B.11.126. [S]. Lemon Juice

(a) shall be the fruit juice obtained from lemons;
13-5-75 (b) shall contain, before the addition of a sweetening ingredient, in 100 millilitres measured at a temperature of 20°C, not less than
(i) 8.0 grams of soluble solids, as determined by official method FO-26, Determination of Soluble Solids in Lemon Juice, Lime Juice or Lime Fruit Juice, October 15, 1981, and
5-8-82 (ii) 5.0 grams of acid calculated as anhydrous citric acid, as determined by official method FO-27, Determination of Acid in Lemon Juice, Lime Juice, or Lime Fruit Juice, October 15, 1981;
13-5-75 (c) may contain stannous chloride; and
18-1-90 (d) may contain a sweetening ingredient in dry form, a Class II preservative, amylase, cellulase, and pectinase.

B.11.127. [S]. Lime Juice or **Lime Fruit Juice**

(a) shall be the fruit juice obtained from limes;
3-9-64 (b) shall have
(i) a specific gravity of not less than 1.030 and not more than 1.040 (20°C/20°C),
(ii) its optical rotation between +0.5 and -1.5 degrees Ventzke, determined at a temperature of 20°C., using a tube 200 millimetres in length;
(c) shall contain, before the addition of a sweetening ingredient, in 100 millilitres measured at a temperature of 20°C, not less than
13-5-75 (i) 8.0 grams of soluble solids, as determined by official method FO-26, Determination of Soluble Solids in Lemon Juice, Lime Juice or Lime Fruit Juice, October 15, 1981, and
5-8-82 (ii) 5.5 grams of acid calculated as anhydrous citric acid, as determined by official method FO-27, Determination of Acid in Lemon Juice, Lime Juice or Lime Fruit Juice, October 15, 1981;
13-5-75 (d) may contain stannous chloride; and
18-1-90 (e) may contain a sweetening ingredient in dry form, a Class II preservative, amylase, cellulase and pectinase.

B.11.128. [S]. Orange Juice

30-4-74 (a) shall be fruit juice obtained from clean, sound, mature oranges;
(b) shall
(i) contain not less than 1.20 milliequivalents of free amino acids per 100 millilitres, as determined by official method FO-21, Determination of Amino Acids in Grapefruit Juice and Orange Juice, October 15, 1981,
(ii) contain not less than 115 milligrams of potassium per 100 millilitres, as determined by official method FO-22, Determination of Potassium in Grapefruit Juice and Orange Juice, October 15, 1981, and
(iii) have an absorbance value for total polyphenolics of not less than 0.380, as determined by official method FO-23, Determination of Absorbance Value for Total Polyphenolics in Grapefruit Juice and Orange Juice, October 15, 1981;
5-8-82 (c) shall, before the addition of sugar, invert sugar, dextrose or glucose solids,
(i) have a Brix reading of not less than 9.7°, as determined by official method FO-24, Determination of Brix Reading for Grapefruit Juice and Orange Juice, October 15, 1981, and
(ii) contain not less than 0.5 per cent and not more than 1.8 per cent of acid by weight calculated as anhydrous citric acid, as determined by official method FO-25, Determination of Acid in Grapefruit Juice or Orange Juice, October 15, 1981;
30-4-74 (d) may contain orange essences, orange oils and orange pulp adjusted in accordance with good manufacturing practice; and
18-1-90 (e) may contain sugar, invert sugar, dextrose in dry form, glucose solids, a Class II preservative, amylase, cellulase and pectinase.

B.11.128A [S]. Pineapple Juice

28-6-68 (a) shall be the fruit juice obtained from pineapple; and
31-12-90 (b) may contain a sweetening ingredient in dry form, a Class II preservative, vitamin C, amylase, cellulase, pectinase and an antifoaming agent.

3-9-64 **B.11.129. [S]. Carbonated (naming the fruit) Juice** or **Sparkling (naming the fruit) Juice** shall be the named fruit juice impregnated with carbon dioxide under pressure.

B.11.130. [S]. (1) **Concentrated (naming the fruit) juice**

(a) shall be fruit juice that is concentrated to at least one half of its original volume by the removal of water;
(b) may contain
6-4-89 (i) vitamin C,
(ii) food colour,
(iii) stannous chloride,
(iv) a sweetening ingredient, and
(v) a class II preservative; and
(c) may have added to it, for the purpose of adjustment in accordance with good manufacturing practice, all or any of the following, namely,
31-1-91 (i) essence, oil and pulp from the named fruit, and
(ii) water.

(2) Subparagraphs (1)(b)(i), (ii), (iii) and (v) do not apply in respect of frozen concentrated orange juice.

3-9-64 **B.11.131. [S]. (Naming the fruits) Juice** shall be a mixture of fruit juices each of which meets the standard prescribed for that fruit juice in this Division.

B.11.132. [S]. Apple and (naming the fruit) Juice

15-6-67 (a) shall be a mixture of apple juice and another fruit juice, each of which meets the standard, if any, prescribed for that fruit juice in this Division; and
(b) may contain added vitamin C.

B.11.133. [S]. Reconstituted (naming the fruit) Juice or **(naming the fruit) Juice from Concentrate**

15-8-57 (a) shall be fruit juice that has been prepared by the addition of water to fruit juice of the same name from which water has been removed;
9-8-78 (b) may contain juice of the same name, a sweetening ingredient, and natural pulp, oils and esters of the named fruit;
(c) shall conform to the standards for the named fruit juices as prescribed in this Division; and
3-2-77 (d) may contain, in the case of reconstituted lemon or lime juice, not more than 10 parts per million dimethylpolysiloxane.

B.11.134. [S]. Apricot Nectar, Peach Nectar or **Pear Nectar**

(a) shall be the unfermented but fermentable pulpy product, intended for direct consumption, obtained by blending the total edible part of sound and ripe apricots, peaches or pears, as the case may be, concentrated or unconcentrated with water and, subject to subparagraph (e)(i); a sweetening ingredient;
(b) shall contain
(i) in the case of peach nectar and pear nectar, not less than 40 per cent by weight of the fruit or the equivalent derived from the concentrated fruit, and
(ii) in the case of apricot nectar, not less than 35 per cent by weight of the fruit or the equivalent derived from the concentrated fruit;

13-9-79 (c) shall contain not less than 13 per cent soluble solids by weight expressed as °Brix on the International Sucrose Scales and calculated by refractometer at 20°C and uncorrected for acidity;
(d) shall not contain more than 3g/kg (3000 ppm) of ethanol and 10 mg/kg (10 ppm) of hydroxy methyl furfural; and
(e) may contain
(i) honey if no other sweetening ingredient is employed,
(ii) citric acid and malic acid at levels consistent with good manufacturing practice,
(iii) lemon juice, and
(iv) vitamin C.

NOTE: Effective January 1, 1979 the following heading and sections will be added

Fruit Flavoured Drinks

B.11.150. No person shall label, package, sell or advertise a fruit flavoured drink in a manner that is likely to create an impression that the fruit flavoured drink contains vitamins or has any other nutritional value commonly associated with any fruit juice unless the following requirements are met:

(a) it is sold as a substitute for fruit juice or as a breakfast drink;
(b) it is not carbonated;
(c) it is not represented to be or is not commonly known as
  (i) a soft drink, or
  (ii) a thirst-quenching or refreshment drink; and

(d) notwithstanding sections D.01.009, D.01.011 and D.02.009,
  (i) it contains vitamin C in an amount not less than 24 milligrams and not more than 48 milligrams, and
  (ii) it contains
    (A) where folic acid has been added, an amount of folic acid of not less than 40 micrograms and not more than 80 micrograms,
    (B) where thiamine has been added, an amount of thiamine of not less than 0.08 milligram and not more than 0.11 milligram,
18-5-78
    (C) where iron has been added, an amount of iron of not less than 0.56 milligram and not more than 0.80 milligram, or
    (D) where potassium has been added, an amount of potassium of not less than 100 milligrams and not more than 200 milligrams,

per 100 millilitres when the drink is ready-to-serve.

B.11.151. No person shall label, package, sell or advertise a base, concentrate or mix that is used for making a fruit flavoured drink in a manner that is likely to create an impression that the drink made therefrom will contain vitamins or have any other nutritional value commonly associated with fruit juice unless the following requirements are met:

(a) the base, concentrate or mix
  (i) is sold for the purpose of making a breakfast drink or a substitute for fruit juice,
  (ii) is not represented to be or is not commonly known as a product that is used for making a soft drink or a thirst-quenching or refreshment drink; and

(b) where a drink is made therefrom as directed, the drink meets the requirements described in paragraph B.11.150(d).

Jams

B.11.201. [S]. (naming the fruit) Jam

(a) shall be the product obtained by processing fruit, fruit pulp, or canned fruit, by boiling to a suitable consistency with water and a sweetening ingredient;

(b) shall contain not less than

18-6-92 (i) 45 per cent of the named fruit, and

(ii) 66 per cent water soluble solids estimated by the refractometer;

3-9-64 (c) may contain

(i) such amount of added pectin, pectinous preparation, or acid ingredient as reasonably compensates for any deficiency in the natural pectin content or acidity of the named fruit,

(ii) a Class II preservative,

25-3-65 (iii) a pH adjusting agent, and

(iv) an antifoaming agent; and

(d) shall not contain apple or rhubarb.

B.11.202. [S]. (naming the fruit) Jam with Pectin

(a) shall be the product obtained by processing fruit, fruit pulp, or canned fruit by boiling to a suitable consistency with water and a sweetening ingredient;

(b) shall contain

18-6-92 (i) not less than 27 per cent of the named fruit,

(ii) not less than 66 per cent water soluble solids as estimated by the refractometer, and

3-9-64 (iii) pectin or pectinous preparations;

(c) may contain

(i) such amount of acid ingredients as reasonably compensates for any deficiency in the natural acidity of the named fruit,

(ii) food colour,

(iii) a Class II preservative,

25-3-65 (iv) a pH adjusting agent, and

(v) an antifoaming agent; and

(d) shall not contain apple or rhubarb.

B.11.203. [S]. Apple (or Rhubarb) and **(naming the fruit) Jam**

(a) shall be the product obtained by processing fruit, fruit pulp or canned fruit by boiling to a suitable consistency with water and a sweetening ingredient;
(b) shall contain not less than
(i) 12.5 per cent of the named fruit, except that where the named fruit is strawberry it shall contain not less than 15 per cent strawberries,
3-9-64 (ii) 20 per cent apple or rhubarb pulp, and
(iii) 66 per cent water soluble solids as estimated by the refractometer; and

(c) may contain
(i) pectin or pectinous preparation,
(ii) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the fruit used in its preparation,
(iii) food colour,
(iv) a Class II preservative,
25-3-65 (v) a pH adjusting agent, and
(vi) an antifoaming agent.

13-5-75 **B.11.204.** Where a jam for which a standard is prescribed in section B.11.203 contains added pectin or pectinous preparation, a statement to the effect that pectin or pectinous preparation has been added shall be shown on the principal display panel.

Marmalade

B.11.220. [S]. (naming the citrus fruit) Marmalade shall be the food of jelly-like consistency made from any combination of peel, pulp or juice of the named citrus fruit by boiling with water and a sweetening ingredient and shall contain not less than 65 per cent water soluble solids as estimated by the refractometer and may contain
3-9-65
(a) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the named citrus fruit;
25-3-65 (b) a pH adjusting agent; and
(c) an antifoaming agent.

B.11.221. [S]. (naming the citrus fruit) Marmalade with Pectin

(a) shall be the food of jelly-like consistency made from any combination of peel, pulp or juice of the named citrus fruit by boiling with water and a sweetening ingredient;
(b) shall contain
(i) not less than 27 per cent of any combination of peel, pulp or juice of the named citrus fruit,
3-9-64 (ii) not less than 65 per cent water soluble solids as estimated by the refractometer, and
(iii) pectin or pectinous preparation; and

(c) may contain
(i) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the citrus fruit used in its preparation,
(ii) a Class II preservative,
25-3-65 (iii) a pH adjusting agent, and
(iv) an antifoaming agent.

B.11.222. [S]. Pineapple Marmalade or **Fig Marmalade**

3-9-64 (a) shall be the food of jelly-like consistency made from the pulp or juice of the named fruit by boiling with water and a sweetening ingredient;

(b) shall contain not less than
3-9-64 (i) 45 per cent of the named fruit, and
(ii) 65 per cent water soluble solids, as estimated by the refractometer;

(c) may contain such amounts of added pectin, pectinous preparation or acid ingredient as reasonably compensates for any deficiency in the natural pectin content or acidity of the named fruit;
25-3-65 (d) a pH adjusting agent; and
(e) an antifoaming agent.

B.11.223. [S]. Pineapple Marmalade with Pectin or **Fig Marmalade with Pectin**

12-4-84 (a) shall be the food of jelly-like consistency made from the pulp and juice of the named fruit by boiling with water and a sweetening ingredient;
(b) shall contain
(i) not less than 27 per cent of the named fruit,
3-9-64 (ii) not less than 65 per cent water soluble solids as estimated by the refractometer, and
(iii) pectin or pectinous preparation; and

(c) may contain
(i) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the named fruit,
(ii) food colour,
(iii) a Class II preservative,
25-3-65 (iv) a pH adjusting agent, and
(v) an antifoaming agent.

B.11.224. [S]. (Naming the fruit) Preserve (Conserve) shall be the food made by processing fruit other than apple or rhubarb with a sweetening ingredient and shall contain not less than

24-6-75 (a) 45 parts by weight of the named fruit for each 55 parts by weight, on the dry basis, of a sweetening ingredient; and
(b) 60 per cent water-soluble solids, as estimated by the refractometer.

Jelly

3-9-64 **B.11.240. [S]. (Naming the fruit) Jelly** shall be the gelatinous food, free of seeds and pulp, made from the named fruit, the juice of the named fruit or a concentrate of the juice of the named fruit, which has been boiled with water and a sweetening ingredient, shall contain not less than 62 per cent water soluble solids as estimated by the refractometer and may contain

(a) such amount of added pectin, pectinous preparation or acid ingredient as reasonably compensates for any deficiency of the natural pectin content or acidity of the named fruit;
25-3-65 (b) a pH adjusting agent; and
(c) an antifoaming agent.

B.11.241. [S]. (Naming the fruit) Jelly with Pectin

(a) shall be the gelatinous food, free of seeds and pulp, made from the named fruit, the juice of the named fruit or a concentrate of the juice of the named fruit, which has been boiled with water and a sweetening ingredient;
(b) shall contain
(i) not less than the equivalent of 32 per cent juice of the named fruit,
(ii) not less than 62 per cent water soluble solids, as estimated by the refractometer, and
3-9-64 (iii) pectin or pectinous preparation; and

(c) may contain
(i) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the named fruit,
(ii) juice of another fruit,
(iii) a gelling agent,
(iv) food colour,

25-3-65 (v) a Class II preservative,
(vi) a pH adjusting agent, and
(vii) an antifoaming agent.

3-9-64 **B.11.242.** The standards prescribed in these Regulations for jam and jelly do not apply to cranberry sauce, jellied cranberry, cranberry jelly, mint jelly and jellied mint.

Mince Meat

B.11.250. [S]. **Mince, Mince Meat** or **Fruit Mince**

(a) shall be the food prepared from
(i) fruit or dried fruit,
(ii) suet,
(iii) salt,
(iv) spices, and
(v) a sweetening agent; and

3-9-64 (b) may contain
(i) vinegar,
(ii) fresh, concentrated or fermented fruit juice,
(iii) spirituous liquor,
(iv) nuts,
(v) cooked meat,
(vi) a Class II preservative,
(vii) a thickening agent,
(viii) citric acid, and
13-5-76 (ix) caramel.

Boiled Cider

3-9-64 **B.11.260. [S].** **Boiled Cider** shall be the liquid expressed from whole apples, apple cores, apple trimmings or apple culls and concentrated by boiling.

*(R) Minor correction

Prepackaged Water and Ice

31-7-80 **B.12.001. [S].** Water represented as mineral water or spring water,

(a) shall be potable water obtained from an underground source but not obtained from a public community water supply;

5-8-82 (b) shall not contain any coliform bacteria, as determined by official method MFO-9, Microbiological Examination of Mineral Water, November 30, 1981;

(c) shall not have its composition modified through the use of any chemicals; and

(d) notwithstanding paragraph (c), may contain

(i) added carbon dioxide,

31-7-80 (ii) added fluoride, if the total fluoride ion content thereof does not exceed 1 part per million, and

(iii) added ozone.

23-6-88 **B.12.002.** The principal display panel of the label on a container of water represented as mineral water or spring water shall carry a statement

4-10-73 (a) of the geographical location of the underground source from which it is obtained;

(b) of the total dissolved mineral salt content expressed in parts per million;

(c) of the total fluoride ion content expressed in parts per million; and

(d) of any addition of fluoride or ozone thereto.

23-6-88 **B.12.003.** Where carbon dioxide has been added to water represented as mineral water or spring water, the word "carbonated" ("gazéifiée") shall appear on the principal display panel of the label on the container thereof, as the first designation in the common name of the water when the added carbon dioxide

(a) did not originate from decarbonation of the water upon emergence from the underground source; or

(b) is present in a quantity greater than was present originally in the water.

B.12.004. No person shall sell water in sealed containers, other than water represented as mineral water or spring water, if it contains

(a) any coliform bacteria, as determined by official method MFO-15, Microbiological Examination of Water in Sealed Containers (Excluding Mineral and Spring Water) and of Prepackaged Ice, November 30, 1981;

5-8-82 (b) more than 100 total aerobic bacteria per millilitre, as determined by official method MFO-15, Microbiological Examination of Water in Sealed Containers (Excluding Mineral and Spring Water) and of Prepackaged Ice, November 30, 1981;

(c) naturally occurring fluoride ion in an amount that exceeds its naturally occurring amount; or

(d) added fluoride in such an amount that the total amount therein of added and naturally occurring fluoride ion exceeds 1 part per million.

31-7-80 **B.12.005.** (1) No person shall sell prepackaged ice if it contains

5-8-82 (a) any coliform bacteria as determined by the official method, MFO-15, Microbiological Examination of Water in Sealed Containers (Excluding Mineral and Spring Water) and of Prepackaged Ice, November 30, 1981;

(b) naturally occurring fluoride ion in an amount that exceeds its naturally occurring amount; or

31-7-80 (c) added fluoride in such an amount that the total amount therein of added and naturally occurring fluoride ion exceeds 1 part per million.

(2) No person shall manufacture prepackaged ice for sale if the water from which it is made contains

5-8-82 (a) any coliform bacteria, as determined by official method MFO-15, Microbiological Examination of Water in Sealed Containers (Excluding Mineral and Spring Water) and of Prepackaged Ice, November 30, 1981;

(b) naturally occurring fluoride ion in an amount that exceeds its naturally occurring amount; or

(c) added fluoride in such an amount that the total amount therein of added and naturally occurring fluoride ion exceeds 1 part per million.

*(R) Minor correction

B.12.006. The common name of water in sealed containers, other than water represented as mineral water or spring water, shall be "Water", modified by the word

(a) "Distilled" when the treatment of the water includes its vaporization and condensation;
(b) "Demineralized" when the treatment of the water is such that the mineral content of the water is reduced, by means other than distillation, to less than 10 parts per million; and
31-7-80 (c) "Carbonated" when the water contains added carbon dioxide.

B.12.007. Notwithstanding section B.01.008, when chlorine or any compounds of chlorine have been

(a) used in the treatment of water in sealed containers, other than water represented as mineral water or spring water, and
(b) subsequently removed from the water together with any chlorine and compounds of chlorine produced in the water,

chlorine or any compounds of chlorine need not be shown as ingredients on any part of the label on a sealed container of that water.

13-9-00 **B.12.008.** A statement of the total fluoride ion content expressed in parts per million shall appear on the principal display panel of the label on a sealed container of water, other than water represented as mineral water or spring water and on the label on a container of prepackaged ice.

13-9-00 **B.12.009.** The label on a sealed container of water, other than water represented as mineral water or spring water, shall bear a description on its principal display panel of any treatment the water has undergone, with the exception of the following:

(a) the addition of an ingredient declared in the list of ingredients;
31-7-80 (b) chlorination followed by the removal of the agent used for the chlorination together with any chlorine and compounds of chlorine produced in the water;
(c) decantation; and
(d) filtration.

B.13.001. [S]. Flour, White Flour, Enriched Flour or **Enriched White Flour**

25-8-76 (a) shall be the food prepared by the grinding and bolting through cloth having openings not larger than those of woven wire cloth designated "149 microns (No. 100)", of cleaned milling grades of wheat;

(b) shall be free from bran coat and germ to such an extent that the percentage of ash therein, before the addition of any other material permitted by this section, calculated on a moisture-free basis, does not exceed 1.20 per cent;

(c) shall have a moisture content of not more than 15 per cent;

(d) shall contain in 100 grams of flour

(i) 0.64 milligram of thiamine,

5-11-98 (ii) 0.40 milligram of riboflavin,

(iii) 5.30 milligrams of niacin or niacinamide,

(iv) 0.15 milligram of folic acid, and

(v) 4.4 milligrams of iron;

(e) may contain

(i) malted wheat flour,

(ii) malted barley flour in an amount not exceeding 0.50 per cent of the weight of the flour,

3-4-03 (iii) amylase, amylase (maltogenic), bromelain, glucoamylase, glucose oxidase, lactase, lipase, lipoxidase, pentosanase, protease, pullulanase or xylanase,

(iv) chlorine,

25-8-76 (v) chlorine dioxide,

31-7-80 (vi) benzoyl peroxide in an amount not exceeding 150 parts by weight for each 1 million parts of flour, with or without not more than 900 parts by weight for each 1 million parts of flour of one or a mixture of two or more of calcium carbonate, calcium sulphate, dicalcium phosphate, magnesium carbonate, potassium aluminum sulphate, sodium aluminum sulphate, starch and tricalcium phosphate as carriers of the benzoyl peroxide,

1-3-94 (vii) Revoked by P.C. 1994-362 of March 1, 1994.

(viii) ammonium persulphate in an amount not exceeding 250 parts by weight for each 1 million parts of flour,

(ix) ammonium chloride in an amount not exceeding 2,000 parts by weight for each 1 million parts of flour,

(x) acetone peroxide,

(xi) azodicarbonamide in an amount not exceeding 45 parts by weight for each 1 million parts of flour,

(xii) ascorbic acid in an amount not exceeding 200 parts by weight for each 1 million parts of flour,

25-8-76 (xiii) l-cysteine (hydrochloride) in an amount not exceeding 90 parts by weight for each 1 million parts of flour,

(xiv) monocalcium phosphate in an amount not exceeding 7,500 parts by weight for each 1 million parts of flour, and

(xv) in 100 grams of flour

5-11-98 (A) 0.31 milligram of vitamin B_6,

(B) 1.3 milligrams of *d*-pantothenic acid, and

(C) 190 milligrams of magnesium; and

5-11-98 (f) may contain calcium carbonate, edible bone meal, chalk (B.P.), ground limestone or calcium sulphate in an amount that will provide in 100 grams of flour 140 milligrams of calcium.

19-3-97 (g) Repealed by P.C. 1997-381 of March 19, 1997.

5-11-98 **B.13.002.** Notwithstanding section B.13.001, flour, white flour, enriched flour or enriched white flour, used in or sold for the manufacture of gluten or starch is not required to contain added thiamine, riboflavin, niacin, folic acid or iron.

B.13.003. [S]. Vitamin B White Flour (Canada Approved)

(a) shall be flour that has been milled in such a way as to retain a high proportion of the vitamins naturally occurring in the original wheat berry;
(b) shall constitute not less than 70 per cent of the wheat from which it is milled;
3-9-64 (c) shall be bolted through at least one cloth having openings not larger than those of woven wire cloth designated "149 microns (No. 100)"; and
(d) shall contain, on a moisture-free basis,
(i) in one pound an amount of the vitamin B complex that will contribute not less than 1.2 milligrams of thiamine, and
(ii) not more than 0.70 per cent and not less than 0.61 per cent ash.

B.13.004. [S]. Revoked by P.C. 1979-675 of March 8, 1979.

3-9-64 **B.13.005. [S]. Whole Wheat Flour** or **Entire Wheat Flour**

(a) shall be the food prepared by the grinding and bolting of cleaned, milling grades of wheat from which a part of the outer bran or epidermis layer may have been separated;
(b) shall contain the natural constituents of the wheat berry to the extent of not less than 95 per cent of the total weight of the wheat from which it is milled;
(c) shall have
(i) an ash content, calculated on a moisture-free basis, of not less than 1.25 per cent and not more than 2.25 per cent,
(ii) a moisture content of not more than 15 per cent, and
(iii) such a degree of fineness that not less than 90 per cent bolts freely through a No. 8 (2380 micron) sieve, and not less than 50 per cent through a No. 20 (840 micron) sieve; and
(d) may contain
(i) malted wheat flour,
(ii) malted barley flour in an amount not exceeding 0.50 per cent of the weight of the flour,
3-4-03 (iii) amylase, amylase (maltogenic), bromelain, glucoamylase, glucose oxidase, lactase, lipase, lipoxidase, pentosanase, protease, pullulanase or xylanase,
(iv) chlorine,
(v) chlorine dioxide,
(vi) benzoyl peroxide in an amount not exceeding 150 parts by weight for each 1 million parts of flour, with or without not more than 900 parts by weight for each 1 million parts of flour of one or a mixture of two or more of calcium carbonate, calcium sulphate, dicalcium phosphate, magnesium carbonate, potassium aluminum sulphate, sodium aluminum sulphate, starch and tricalcium phosphate as carriers of the benzoyl peroxide,
1-3-94 (vii) Revoked by P.C. 1994-362 of March 1, 1994.
(viii) ammonium persulphate in an amount not exceeding 250 parts by weight for each 1 million parts of flour,
(ix) ammonium chloride in an amount not exceeding 2,000 parts by weight for each 1 million parts of flour,
(x) azodicarbonamide in an amount not exceeding 45 parts by weight for each 1 million parts of flour,
(xi) acetone peroxide,
(xii) ascorbic acid in an amount not exceeding 200 parts by weight for each 1 million parts of flour,
(xiii) l-cysteine (hydrochloride) in an amount not exceeding 90 parts by weight for each 1 million parts of flour.
19-3-97 (e) Repealed by P.C. 1997-381 of March 19, 1997

B.13.006. [S]. Graham Flour shall be flour to which has been added part of the bran and other constituents of the wheat berry, and shall have an ash content, calculated on a moisture-free basis, of not less than 1.20 per cent and not more than 2.25 per cent.

B.13.007. [S]. Gluten Flour shall be the food obtained by removing from flour a part of the starch and shall not contain more than

(a) 10 per cent moisture; and

5-8-82 (b) 44 per cent Starch, calculated on a moisture-free basis, as determined by official method FO-28, Determination of Starch in Gluten Flour, October 15, 1981.

3-9-64 **B.13.008. [S]. Crushed Wheat** or **Coarse Ground Wheat** shall be the food prepared by so crushing cleaned wheat that 40 per cent or more passes through a No. 8 (2380 micron) sieve and less than 50 per cent through a No. 20 (840 micron) sieve, the proportions of the natural constituents of such wheat, other than moisture, remaining unaltered and shall have

(a) an ash content, calculated on a moisture-free basis, of not less than 1.50 per cent and not more than 2.25 per cent; and
(b) a moisture content of not more than 15.5 per cent.

B.13.009. [S]. Cracked Wheat shall be the food prepared by so cracking or cutting cleaned wheat into angular fragments that not less than 90 per cent passes through a No. 8 (2380 micron) sieve and not more than 20 per cent through a No. 20 (840 micron) sieve, the proportions of the natural constituents of such wheat, other than moisture, remaining unaltered and shall have

(a) an ash content, calculated on a moisture-free basis, of not less than 1.50 per cent and not more than 2.25 per cent; and
(b) a moisture content of not more than 15.5 per cent.

27-4-78 **B.13.010. [S]. Rice** shall be the hulled or hulled and polished seed of the rice plant and, in the case of hulled and polished seeds, may be coated with magnesium silicate, talc and glucose.

B.13.010.1 (1) For the purposes of this Division, pre-cooked rice means polished rice that has been cooked in water or steam and dried in such a manner as to retain the rice grains in a porous and open-structured condition.

(2) Notwithstanding sections D.01.009, D.01.011 and D.02.009, no person shall sell pre-cooked rice to which a vitamin or mineral nutrient set out in column I of an item of the table to this section has been added, either singly or in any combination, unless each 100 g of the pre-cooked rice as sold contains the added vitamin or mineral nutrient in the amount set out in column II of that item.

13-3-86 **TABLE**

Item	*Column I* *Vitamin or Mineral Nutrient*	*Column II* *Amount per 100 g of Pre-cooked Rice*
1.	Thiamine	0.45 mg
2.	Niacin	4.2 mg
3.	Vitamin B_6	0.6 mg
4.	Folic Acid	0.016 mg
5.	Pantothenic Acid	1.2 mg
6.	Iron	1.6 mg

(3) No person shall represent pre-cooked rice as "enriched" unless the food contains added thiamine, niacin and iron.

13-5-75 **B.13.011. [S].** Corn starch shall be starch made from maize and shall contain not less than 84 per cent starch.

B.13.014. For the purpose of this DIVISION moisture, ash and fineness shall be determined by the following applicable official methods:

(a) FO-29, Determination of Moisture in Grain, October 15, 1981;
5-8-82 (b) FO-30, Determination of Ash in Grain, October 15, 1981; and
(c) FO-31, Determination of Degree of Fineness of Grain, October 15, 1981.

10-12-74 **B.13.015. [S]. Cottonseed Flour** or similar products from cottonseed shall be derived from decorticated, defatted or partially defatted, cooked, ground cottonseed kernels and contain not more than 450 parts per million of free gossypol.

Bread

23-3-89 **B.13.020.** In this Division, "milk solids" means the entire solids content from milk, partly skimmed milk or skim milk or their concentrated, dried or reconstituted form, singly or in any combination.

B.13.021. [S]. Bread or **White Bread** shall be the food made by baking a yeast-leavened dough prepared with flour and water and may contain

(a) salt;
(b) shortening, lard, butter or margarine;
3-9-64 (c) milk or milk product;
(d) whole egg, egg-white, egg-yolk, (fresh, dried, or frozen);
(e) a sweetening agent;
(f) malt syrup, malt extract or malt flour;
(g) inactive dried yeast of the genus Saccharomyces cerevisiae in an amount not greater than 2 parts by weight for each 100 parts of flour used;
3-4-03 (h) amylase, amylase (maltogenic), bromelain, glucoamylase, glucose oxidase, lactase, lipase, lipoxidase, pentosanase, protease, pullulanase or xylanase;
8-3-79 (i) subject to section B.13.029, one or more of the following in a total amount not exceeding 5 parts by weight per 100 parts of flour used, namely, whole wheat flour, entire wheat flour, graham flour, gluten flour, wheat meal, wheat starch, non-wheat flour, non-wheat meal or non-wheat starch, any of which may be wholly or partially dextrinized;
(j) other parts of the wheat berry;
15-5-68 (k) lecithin or ammonium salt of phosphorylated glyceride;
1-10-68 (l) monoglycerides and diglycerides of fat-forming fatty acids;
10-3-70 (m) ammonium chloride, ammonium sulphate, calcium carbonate, calcium lactate, diammonium phosphate, dicalcium phosphate, monoammonium phosphate or any combination thereof in an amount not greater than 0.25 parts by weight of all such additives for each 100 parts of flour used;
3-9-69 (n) monocalcium phosphate in an amount not greater than 0.75 parts by weight for each 100 parts of flour used;
1-3-94 (o) calcium peroxide, ammonium persulphate, potassium persulphate or any combination thereof in an amount not greater than 0.01 part by weight of all such additives for each 100 parts of flour used;
3-9-64 (p) acetone peroxide;
(q) vinegar;
(r) Class III preservative;
8-9-66 (s) food colour;
8-3-79 (t) calcium stearoyl-2-lactylate or sodium stearoyl-2-lactylate in an amount not greater than 0.375 parts by weight for each 100 parts of flour used;
8-9-66 (u) l-cysteine (hydrochloride) in an amount not greater than 0.009 parts by weight for each 100 parts of flour used;
(v) calcium sulphate in an amount not greater than 0.5 parts by weight for each 100 parts of flour used;
15-5-68 (w) sodium stearyl fumarate in an amount not greater than 0.5 parts by weight for each 100 parts of flour used;
(x) ascorbic acid in an amount not greater than 0.02 parts by weight for each 100 parts of flour used;
1-10-68 (y) lactic acid;
(z) azodicarbonamide in an amount not exceeding 45 parts by weight for each 1 million parts of flour;
1-4-82 (aa) calcium iodate, potassium iodate or any combination thereof in an amount not greater than 45 parts by weight of all such additives for each 1 million parts of flour, and
1-4-82 (bb) acetylated tartaric acid esters of mono- and diglycerides in an amount not greater than 0.6 parts by weight for each 100 parts of flour used.

B.13.022. [S]. Enriched Bread or **Enriched White Bread**

(a) shall be bread that is baked from a dough in which enriched flour is the only wheat flour used;
(b) shall contain
  (i) for each 100 parts of flour used, not less than
    (A) two parts by weight of skim milk solids,
    (B) four parts by weight of dried whey powder, or
    (C) such amount of the protein product made from peas (*Pisum sativum*) or soybeans (*Glycine max*) as will provide 0.5 parts by weight of protein, and
  (ii) in 100 grams of bread,
    (A) 0.40 milligram of thiamine,
5-11-98 (B) 0.24 milligram of riboflavin,
    (C) 3.3 milligrams of niacin or niacinamide,
    (D) 0.10 milligram of folic acid, and
    (E) 2.76 milligrams of iron;
(c) may contain, in 100 grams of bread,
  (i) 0.14 milligram of vitamin B_6,
5-11-98 (ii) 0.6 milligram of *d*-pantothenic acid,
  (iii) 90 milligrams of magnesium, and
  (iv) 66 milligrams of calcium; and
(d) where it contains not less than 6 parts by weight of milk solids per 100 parts of enriched flour used, may be described by the common name "milk bread".

B.13.023. Revoked by P.C. 1979-675 of March 8, 1979.

B.13.024. Revoked by P.C. 1979-675 of March 8, 1979.

3-9-64 **B.13.025. [S]. Raisin Bread** shall be bread that contains for each 100 parts by weight of flour used not less than 50 parts by weight of seeded or seedless raisins, or raisins and currants of which not less than 35 parts shall be raisins and may contain spices or peel.

B.13.026. [S].(naming the percentage) Whole Wheat Bread

(a) shall
  (i) be bread in the making of which the named percentage of the flour used shall be whole wheat flour, and
23-3-89 (ii) contain not less than 60 per cent whole wheat flour in relation to the total flour used; and
(b) may
  (i) contain caramel, and
  (ii) where it contains not less than 6 parts by weight of milk solids per 100 parts of the total enriched flour and whole wheat flour used, be described by the common name "(naming the percentage) whole wheat milk bread".

B.13.027. [S]. Brown Bread shall be bread coloured by the use of whole wheat flour, graham flour, bran, molasses or caramel.

19-3-97 **B.13.028.** Revoked by P.C. 1997-381 of March 19, 1997.

B.13.029. A specialty bread may contain

8-3-79

(a) one or more of the ingredients specified in paragraph B.13.021(i) in a total amount greater than the total amount specified in that paragraph; and
(b) fruits, nuts, seeds and flavouring.

Alimentary Paste

31-1-66 **B.13.051.** No person shall sell macaroni, spaghetti, noodles or similar alimentary pastes, as egg macaroni, egg spaghetti, egg noodles or egg alimentary pastes, respectively, unless they contain, on the dry basis, not less than 4 per cent egg-yolk solids derived from whole egg, dried egg, frozen egg or frozen egg-yolk.

1-11-94 **B.13.052.** (1) Notwithstanding sections D.01.009, D.01.011 and D.02.009, no person shall sell an alimentary paste to which a vitamin or a mineral nutrient set out in column I of any item of the table to this section has been added unless each 100 g of the alimentary paste contains the added vitamin or mineral nutrient in an amount not less than the minimum amount set out in column II of that item and not more than the maximum amount set out in column III of that item.

5-11-98 (2) No person shall represent an alimentary paste as "enriched" unless the alimentary paste contains added thiamine, riboflavin, niacin, folic acid and iron, in accordance with the table to this section.

13-1-94 **TABLE**

Item	*Column I* *Added Vitamin or Mineral Nutrient*	*Column II* *Minimum Amount per 100 g of Alimentary Paste*	*Column III* *Maximum Amount per 100 g of Alimentary Paste*
1.	Thiamine	0.63 mg	1.50 mg
2.	Riboflavin	0.11 mg	0.60 mg
3.	Niacin	5.90 mg	7.50 mg
5-11-98 4.	Folic Acid	0.20 mg	0.27 mg
5.	Pantothenic Acid	1.00 mg	2.00 mg
6.	Vitamin B_6	0.40 mg	0.80 mg
7.	Iron	2.90 mg	4.30 mg
8.	Magnesium	150.00 mg	300.00 mg

Breakfast Cereal

B.13.060. Notwithstanding sections D.01.009, D.01.011 and D.02.009, no person shall sell a breakfast cereal to which a vitamin or mineral nutrient set out in column I of an item of the table to this section has been added, either singly or in any combination, unless each 100 g of the breakfast cereal contains the added vitamin or mineral nutrient in the amount set out in column II of that item.

3-11-83 **TABLE**

Item	*Column I* *Vitamin or Mineral Nutrient*	*Column II* *Amount per 100 g of Breakfast Cereal*
1.	Thiamine	2.0 mg
2.	Niacin	4.8 mg
3.	Vitamin B_6	0.6 mg
4.	Folic Acid	0.06 mg
5.	Pantothenic Acid	1.6 mg
6.	Magnesium	160.0 mg
7.	Iron	13.3 mg
9-3-89 8.	Zinc	3.5 mg

*(R) Minor correction

Meat, its Preparation and Products

B.14.001. In this Division

"**animal**" means any animal used as food, but does not include marine and fresh water animals;

13-8-86 "**filler**" means any vegetable material (except tomato or beetroot), milk, egg, yeast or any derivative or combination thereof that is acceptable as food. (*agent de remplissage*)

B.14.002. [S]. Meat shall be the edible part of the skeletal muscle of an animal that was healthy at the time of slaughter, or muscle that is found in the tongue, diaphragm, heart or oesophagus, and may contain accompanying and overlying fat together with the portions of bone, skin, sinew, nerve and blood vessels that normally accompany the muscle tissue and are not separated from it in the process of dressing, but does not include muscle found in the lips, snout, scalp or ears.

3-9-64 **B.14.003. [S].** Meat by-product shall be any edible part of an animal, other than meat, that has been derived from one or more animals that were healthy at the time of slaughter.

B.14.004. Meat, meat by-products or preparations thereof are adulterated if any of the following substances or class of substances are present therein or have been added thereto;

(a) mucous membranes, any organ or portions of the genital system, black gut, spleens, udders, lungs or any other organ or portion of animal that is not commonly sold as an article of food;

(b) preservatives other than those provided for in this Division; or

20-11-97 (c) colour other than annatto, allura red and sunset yellow FCF, where provided for in this Division, and caramel.

24-3-94 **B.14.005. [S]. Prepared meat** or a **prepared meat by-product** shall be any meat or any meat by-product, respectively, whether comminuted or not, to which has been added any ingredient permitted by these Regulations, or which has been preserved, placed in a hermetically-sealed container or cooked, and may contain

15-5-68 (a) in the case of prepared hams, shoulders, butts, picnics and backs, gelatin,

(b) in the case of partially defatted pork fatty tissue and partially defatted beef fatty tissue, a Class IV preservative, and

(c) where a minimum total protein content or a minimum meat protein content is prescribed in this Division, phosphate salts that do not when calculated as sodium phosphate, dibasic, exceed the maximum level provided therefor in Table XII to section B.16.100 and that are one or more of the following phosphate salts, namely,

(i) sodium acid pyrophosphate,
(ii) sodium hexametaphosphate,
24-3-94 (iii) sodium phosphate, dibasic,
(iv) sodium phosphate, monobasic,
(v) sodium pyrophosphate, tetrabasic,
(vi) sodium tripolyphosphate,
(vii) potassium phosphate, monobasic,
(viii) potassium phosphate, dibasic, and
(ix) potassium pyrophosphate, tetrabasic.

10-11-76 **B.14.006.** Powdered hydrogenated cottonseed oil in an amount not greater than 0.25 per cent of the product may be applied as a release agent to the surface of meat, meat by-product, prepared meat, prepared meat by-product, extended meat product and simulated meat product.

19-12-79 **B.14.007. [S]. Meat Binder** or **(naming the meat product) Binder** shall be a filler with any combination of salt, sweetening agents, spices or other seasonings (except tomato), egg, egg albumen, and

8-4-75 (a) where sold for use in preserved meat and preserved meat by-product, may contain potassium nitrate, potassium nitrite, sodium nitrate, sodium nitrite, ascorbic acid, sodium ascorbate, erythorbic acid, sodium erythorbate and sodium carbonate, if the nitrate or nitrite salts or both are packaged separately from any spice or seasoning;

25-3-65 (b) where sold for use in prepared meat or meat by-product in which a gelling agent is a permitted ingredient, may contain a gelling agent;

13-8-69 (c) where sold for use in fresh, uncooked sausage, may contain artificial maple flavour, and

7-10-82 (d) may contain an anticaking agent.

12-4-84 **B.14.008.** No person shall sell a meat binder, filler or preparations for pumping pickle, cover pickle or dry cure represented for use in meat products unless the label thereof carries directions for use that when followed will produce a food that will comply with the requirements of section B.14.030 insofar as the filler is concerned and the food will not contain food additives in excess of the maximum levels of use prescribed by these regulations.

B.14.009. [S]. Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product may contain

13-9-79 (a) Class I preservatives if the nitrate or nitrite salts or both are packaged separately from any spice or seasoning;
(b) citric acid, sodium citrate or vinegar;
19-12-79 (c) sweetening agents, including maple sugar and maple syrup;
16-8-94 (d) liquid smoke flavour, liquid smoke flavour concentrate, salt, seasonings, spices, spice extracts, spice oils or spice oleoresins;
5-4-77 (e) sodium bicarbonate, sodium hydroxide or potassium hydroxide;
10-6-82 (f) in the case of pumping pickle for cured pork, beef and lamb cuts, disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate and sodium acid pyrophosphate in such amount calculated as disodium phosphate, as will result in the finished product containing not more than 0.5 per cent added phosphate;
23-6-88 (g) in the case of pumping pickle for cured beef cuts, enzymes, if the principal display panel of the label of the cured beef carries, immediately preceding or following the common name, the statement "Tenderized with (naming the proteolytic enzyme or enzymes)";
5-10-71 (h) in the case of dry cure, an anticaking agent or a humectant; and
(i) in the case of pumping pickle
1-10-68 (i) for cured pork hams, shoulders and backs, artificial maple flavour, and
(ii) for cured pork bellies, artificial maple flavour and an orange flavour that meets the standard prescribed in section B.10.005.

8-3-79 **B.14.010.** No person shall sell as food a dead animal or any part thereof.

31-7-61 **B.14.011.** No person shall sell as food, meat, meat by-products, preparations containing meat or meat derivatives obtained, prepared or manufactured from a dead animal.

B.14.012. For the purpose of Sections B.14.010 and B.14.011, "dead animal" means a dead animal that

31-7-61 (a) was not killed for the purpose of food in accordance with commonly accepted practice of killing animals for the purpose of food, which shall include exsanguination, or
(b) was affected with disease at the time it was killed.

19-3-97 **B.14.013** repealed by P.C. 1997-378 of March 19, 1997.

B.14.014 repealed by P.C. 1997-378 of March 19, 1997.

Meats, Meat By-Products

B.14.015. [S]. Regular Ground Beef shall be beef meat processed by grinding and shall contain not more than 30 per cent beef fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981.

5-8-82 **B.14.015A. [S].** **Medium Ground Beef** shall be beef meat processed by grinding and shall contain not more than 23 per cent beef fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981.

B.14.015B. [S]. **Lean Ground Beef** shall be beef meat processed by grinding and shall contain not more than 17 per cent beef fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981.

5-8-82 **B.14.015C.** No person shall sell ground beef that contains more than 30 per cent beef fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981.

B.14.016. No person shall sell horse-meat or horse-meat by-product, or any food containing horse-meat or horse-meat by-product unless

(a) it is labelled as such when offered or exposed for sale; and

23-6-88 (b) when in package form, the principal display panel of the label carries a declaration of the presence of horse-meat or of horse-meat by-product in type at least as legible and conspicuous as any other type upon such principal display panel.

13-8-03 **B.14.017.** Repealed by P.C. 2003-1208 of August 13, 2003.

B.14.018. (1) Subject to subsection (2), if a carcass of beef or veal, or a portion of a carcass of beef or veal that weighs 7 kg or more, is advertised for sale, the advertisement shall indicate

(a) in the case of a carcass other than an imported carcass, the grade that was assigned to the carcass by a grading authority established under the *Canada Agricultural Products Act* or a provincial law;

12-12-02 (b) in the case of an imported beef carcass, the grade that was assigned to the carcass by a grading authority established under the *Canada Agricultural Products Act* or a provincial law or the grade that was assigned to the carcass by a grading authority established under the laws of the country from which the carcass was imported;

(c) in the case of an imported veal carcass, the grade that was assigned to the carcass by a grading authority established under the laws of the country from which the carcass was imported; and

(d) in the case of a beef carcass, the yield class, if any, that was assigned to the carcass by a grading authority established under the *Canada Agricultural Products Act*.

(2) Where, in the case of a carcass referred to in subsection (1), no grade has been assigned thereto as described in that subsection and the carcass or portion thereof that weighs 7 kg or more is advertised for sale, the advertisement shall clearly indicate that the carcass has not been graded.

B.14.019. (1) Where a carcass of beef, veal, pork or lamb or a portion thereof that weighs 7 kg or more is advertised for sale and a selling price is stated in the advertisement, the advertisement shall

29-10-92 (a) contain the words "price per kilogram is based on carcass weight before cutting, boning and trimming" or the words "price per kilogram is based on the weight of the meat after cutting, boning and trimming", whichever words are applicable; and

(b) where in addition to the selling price a charge is payable for cutting, boning, trimming, wrapping or freezing the carcass or portion thereof, indicate

(i) the amount of the additional charge, and

(ii) where the additional charge is payable on a price per unit weight basis, whether the additional charge is based on the weight of the carcass or portion thereof before or after the carcass has been cut, boned and trimmed.

(2) Any information required by subsection (1) to appear in an advertisement shall be located therein immediately adjacent to the selling price stated therein, without any intervening written, printed or graphic matter.

B.14.020. [S]. **Solid cut meat** shall be

24-3-94 (a) a whole cut of meat; or

(b) a product consisting of pieces of meat of which at least 80 per cent weigh at least 25 g each.

B.14.021. (1) No person shall sell solid cut meat to which phosphate salts or water has been added unless

(a) in the case of meat, other than side bacon, Wiltshire bacon, pork jowls, salt pork and salt beef, the meat

(i) where cooked, contains a meat protein content of not less than 12 per cent, and

(ii) where uncooked, contains a meat protein content of not less than 10 per cent; and

(b) that meat contains, phosphate salts that do not when calculated as sodium phosphate, dibasic, exceed the maximum level provided therefor in Table XII to section B.16.100 and that are one or more of the following phosphate salts, namely,

(i) sodium acid pyrophosphate,

(ii) sodium hexametaphosphate,

24-3-94 (iii) sodium phosphate, dibasic,

(iv) sodium phosphate, monobasic,

(v) sodium pyrophosphate, tetrabasic,

(vi) sodium tripolyphosphate,

(vii) potassium phosphate, monobasic,

(viii) potassium phosphate, dibasic, and

(ix) potassium pyrophosphate, tetrabasic.

(2) A bone or a visible fat layer shall not be included in any calculation used to determine meat protein content for the purposes of paragraph (1)(a).

Prepared Meats, Prepared Meat By-Products

B.14.030. (1) Subject to subsections (2) and (3) and section B.14.030A, no person shall sell a prepared meat or prepared meat by-product with a meat protein content of less than 1.5 percentage points below the total protein requirement for that food.

(2) Subsection (1) does not apply to an extended meat product.

13-8-86 (3) Where gelatin is an ingredient of a prepared meat or prepared meat by-product, that gelatin shall not be included when calculating the total protein content of the prepared meat or prepared meat by-product.

B.14.030A. For the purposes of sections B.14.030, B.14.032, B.14.033, B.14.035, B.14.074, B.14.075, B.14.076 and B.14.077, where any of the non-meat ingredients listed in paragraphs B.14.032A (a) to (g) are present in a prepared meat or prepared meat by-product in separate identifiable pieces or chunks in any amount sufficient to differentiate those ingredients from the prepared meat or prepared meat by-product, those ingredients shall not be included when calculating the fat or protein content of the prepared meat or prepared meat by-product.

19-12-79 **B.14.031. [S].** **Preserved Meat** or **Preserved Meat By-product** shall be cooked or uncooked meat or meat by-product that is salted, dried, pickled, corned, cured or smoked, may be glazed and may contain

3-9-64 (a) Class I preservative;

19-12-79 (b) sweetening agents;

(c) spices and seasonings, except tomato;

31-1-66 (d) vinegar;

(e) alcohol;

(f) smoke flavouring or artificial smoke flavouring;

19-3-97 (g) in the case of cured pork hams, shoulders, backs and bellies, artificial maple flavour;

(gg) in the case of cured pork bellies, an added orange flavour that meets the standard prescribed in section B.10.005;

10-12-92 (h) in the case of cured pork, beef and lamb cuts prepared with the aid of pumping pickle, disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate and sodium acid pyrophosphate in such amount calculated as disodium phosphate, as will result in the finished product containing not more than 0.5 per cent added phosphate; and

(i) in the case of tocino, annatto in such amount as will result in the finished product containing not more than 0.1 per cent annatto, if annatto is shown, by the word "annatto", in the list of ingredients on the label.

B.14.032. [S]. Sausage or **Sausage Meat**

19-12-79 (a) shall be fresh or preserved comminuted meat;
(b) may be enclosed in a casing;
19-12-79 (c) may be dipped in vinegar, smoked cooked or dried;
(d) may contain
(i) animal fat,
4-10-65 (ii) filler,
(iii) beef tripe,
(iv) liver,
(v) fresh or frozen beef and pork blood,
(vi) sweetening agents,
19-12-79 (vii) salt and spices,
(viii) seasoning, other than tomato,
(ix) lactic acid producing starter culture,
(x) meat binder,
19-12-79 (xi) beef and pork blood plasma,
19-3-97 (xii) in the case of preserved comminuted meat, smoke flavouring or artificial smoke flavouring,
(xiii) if cooked
(1) glucono delta lactone;
15-5-68 (2) partially defatted beef fatty tissue or partially defatted pork fatty tissue; and
(3) a dried skim milk product, obtained from skim milk by the reduction of its calcium content and a corresponding increase in its sodium content, in an amount not exceeding 3 per cent of the finished food,

19-3-97 (xiv) in the case of fresh uncooked sausage, artificial maple flavour or apple powder as a flavouring ingredient,
10-12-92 (xv) in the case of dry sausage or dry sausage meat, glucono delta lactone; and
20-11-97 (xvi) in the case of longaniza,
(A) annatto in such amount as will result in the finished product containing not more than 1000 parts per million annatto, if annatto is shown, by the word "annatto", in the list of ingredients on the label,
(B) allura red in such amount as will result in the finished product containing not more than 80 parts per million allura red, if allura red is shown, by the words "allura red", in the list of ingredients on the label, and
(C) sunset yellow FCF in such amount as will result in the finished product containing not more than 20 parts per million sunset yellow FCF, if sunset yellow FCF is shown, by the words "sunset yellow FCF", in the list of ingredients on the label.

5-8-82 (e) shall contain, in the case of a product sold as fresh sausage, not more than 40 per cent fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;
(f) shall have, if cooked, a total protein content of not less than 11 per cent;
(g) shall have, in the case of fresh uncooked sausage and fresh uncooked sausage meat, a total protein content of not less than 9 per cent.

B.14.032A. [S]. (naming the prepared meat or **prepared meat by-product)** with **(naming the non-meat ingredients)** shall be prepared meat to which has been added other non-meat ingredients including

(a) fruit,
(b) vegetables,
(c) nuts,
28-1-75 (d) cheese or processed cheese,
(e) macaroni,
(f) pickles, or
(g) olives.

13-8-86 **B.14.032AA.** Where the non-meat ingredients referred to in section B.14.032A are added to prepared meat in such a manner that they are not present in the final product in separate identifiable pieces or chunks, the final product shall meet the total protein content requirement established for (naming the prepared meat or prepared meat by-product) referred to in section B.14.032A.

19-12-79 **B.14.033. [S]. Potted Meat, Meat Paste** or **Meat Spread** shall be comminuted and cooked, fresh or preserved meat and may contain meat binder, salt, sweetening agent, spices, other seasonings and a gelling agent and shall have a total protein content of not less than 9 per cent.

*(R) Minor correction

9-8-78 **B.14.034. [S].** **Potted Meat By-product, Meat By-product Paste** or **Meat By-product Spread** shall be a food that

(a) consists, wholly or in part, of meat by-products and conforms to the standard prescribed for potted meat; and

13-8-86 (b) in the case of liverpaste or liverwurst spread, may contain wheat germ and yeast.

19-12-79 **B.14.035. [S].** **Meat Loaf, Meat Roll, Meat Lunch** or **Luncheon Meat** shall be comminuted and cooked, fresh or preserved meat, pressed into shape and may contain a dried skim milk product obtained from skim milk by the reduction of its calcium content and a corresponding increase in its sodium content, in an amount not exceeding 3 per cent of the finished food, filler, meat binder, salt, sweetening agents, glucono delta lactone, spices, other seasonings, milk, eggs, a gelling agent and partially defatted beef fatty tissue or partially defatted pork fatty tissue and shall have a total protein content of not less than 11 per cent.

B.14.036. [S]. **Meat By-product Loaf** or **Meat and Meat By-product Loaf** shall be the food consisting, wholly or in part, of meat by-products and shall otherwise conform to the standard prescribed for meat loaf.

B.14.037. [S]. Headcheese

(a) shall be comminuted cooked meat or comminuted cooked preserved meat;
(b) shall not contain
3-9-64 (i) less than 50 per cent head meat, or
(ii) skin, other than that naturally adherent to any pork meat used;

(c) may contain scalps, snouts, beef tripe, salt, spices, seasoning or an added gelling agent; and
26-6-80 (d) may contain
(i) ascorbic acid or its sodium salt, or
(ii) erythorbic acid or its sodium salt.

B.14.038. [S]. **Brawn** shall be headcheese, except that it need not contain 50 per cent head meat.

13-5-75 **B.14.039.** Where a gelling agent has been added to prepared meat or prepared meat by-product, a statement to the effect that a gelling agent has been added shall be shown on the principal display panel or the word "jellied" shall be shown as a integral part of the common name of the food.

28-4-77 **B.14.040.** Subject to section B.14.032 and sections B.14.033 to B.14.036, no person shall sell a food that consists of a mixture of ground meat and filler, ground meat by-product and filler or ground meat, ground meat by-product and filler, unless that food

(a) has a total protein content of not less than 13 per cent;
(b) has a fat content of not more than 40 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case of a mixture containing pork meat or pork meat by-product or both; and
5-8-82 (c) has a fat content of not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case of any other meat mixture.

28-4-77 **B.14.041.** Subject to section B.14.032 and sections B.14.033 to B.14.036, no person shall sell a food that consists of a mixture of ground meat and spices and seasonings, ground meat by-product and spices and seasonings, ground meat, ground meat by-product and spices and seasonings or ground meat and ground meat by-product, unless that food

(a) has a total protein content of not less than 16 per cent;
(b) has a fat content of not more than 40 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case of a mixture containing pork meat or pork meat by-product or both; and
5-8-82 (c) has a fat content of not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case of any other meat mixture.

Meat Derivatives

25-3-65 **B.14.061. [S].** **Edible Bone Meal** or **Edible Bone Flour** shall be the food prepared by grinding dry defatted bones, obtained from animals healthy at the time of slaughter and shall contain

5-8-82 (a) not less than 85 per cent ash, as determined by official method FO-34, Determination of Ash in Edible Bone Meal or Edible Bone Flour, October 15, 1981;

19-3-97 (b) repealed by P.C. 1997-378 of March 19, 1997;

(c) repealed by P.C. 1997-378 of March 19, 1997.

17-11-77 **B.14.062. [S].** (1) Gelatin or Edible Gelatin

(a) shall be the purified food obtained by the processing of skin, ligaments or bones of animals;

5-8-82 (b) shall contain not less than 82 per cent ash-free solids, when tested by official method FO-35, Determination of Ash-Free Solids in Gelatin, October 15, 1981;

(c) shall be free from objectionable taste and offensive odour when 2.5 grams thereof are dissolved in 100 millilitres of warm water;

19-3-97 (d) repealed by P.C. 1997-378 of March 19, 1997;

17-11-77 (e) shall not contain any residues of hydrogen peroxide where it has been used in the course of manufacture; and

(f) may contain

(i) not more than 2.6 per cent ash on a dry basis,

(ii) not more than 500 parts per million of sulphurous acid, including the salts thereof, calculated as sulphur dioxide, and

(iii) where intended for use in the manufacture of marshmallow, sodium hexametaphosphate or sodium lauryl sulphate.

(2) No person shall use, in the course of manufacturing gelatin or edible gelatin,

26-6-80 (a) acidic or basic compounds other than acetic acid, ammonium hydroxide, citric acid, fumaric acid, hydrochloric acid, lime magnesium hydroside, phosphoric acid, sodium carbonate, sodium hydroxide, sodium sulphide, sulphuric acid, sulphurous acid or tartaric acid; or

16-11-78 (b) filtering and clarifying agents other than activated carbon, alumina, aluminum sulphate, calcium phosphate, dibasic, cellulose, diatomaceous earth, perlite, strongly acidic cation exchange resin in the hydrogen ion form or basic anion exchange resins in the chloride ion or free base ion forms.

Meat Stews

B.14.063. For the purposes of section B.14.064 to B.14.068, "stew meat" means meat that contains when raw not more than

(a) 25 per cent fat, in the case of meat in meat ball stews; and

(b) 20 per cent fat, in the case of meat in other stews.

B.14.064. [S]. **Vegetable Stew with (naming the meat)**

(a) shall contain vegetables and the named meat in the following amounts, calculated as raw ingredients:

(i) 12 per cent or more stew meat, and

(ii) 38 per cent or more vegetables; and

16-11-78 (b) may contain gravy, salt, seasoning and spices.

B.14.065. [S]. **(naming the meat) Stew**

(a) shall contain vegetables and the named meat in the following amounts, calculated as raw ingredients:

(i) 20 per cent or more stew meat, and

(ii) 30 per cent or more vegetables; and

(b) may contain gravy, salt, seasoning and spices.

B.14.066. [S]. Irish Stew

(a) shall contain mutton, lamb or beef, singly or in any combination and vegetables, in the following amounts, calculated as raw ingredients:
  (i) 20 per cent or more stew meat,
  (ii) 30 per cent or more vegetables; and

(b) may contain gravy, salt, seasoning and spices.

B.14.067. [S]. Meat Ball Stew

(a) shall contain vegetables and meat balls in the following amounts, calculated as raw ingredients:
  (i) 22 per cent or more meat balls,
  (ii) 30 per cent or more vegetables; and

(b) may contain gravy, salt, seasoning and spices.

16-11-78 **B.14.068. [S].** Specialty Meat Stews

(a) shall contain meat and vegetables in the following amounts, calculated as raw ingredients:
  (i) 25 per cent or more stew meat,
  (ii) 30 per cent or more vegetables; and

(b) may contain gravy, salt, seasoning and spices.

Meat Specialties

B.14.070. [S]. **Wieners and Beans** or **Wieners with Beans** shall be the food prepared from dried beans and wieners, may contain sauce, seasoning, spices and a sweetening agent, and shall contain not less than 25 per cent wieners, as determined by official method FO-36, Determination of Wiener Content of Meat Specialties, October 15, 1981.

5-8-82 **B.14.071. [S].** **Beans and Wieners** or **Beans with Wieners** shall be the food prepared from dried beans and wieners, may contain sauce, seasoning, spices and a sweetening agent and shall contain not less than 10 per cent wieners, as determined by official method FO-36, Determination of Wiener Content of Meat Specialties, October 15, 1981.

20-2-73 ## Sale of Barbecued, Roasted or Broiled Meat or Meat By-Products

B.14.072. No person shall sell meat or a meat by-product that has been barbecued, roasted or broiled and is ready for consumption unless the cooked meat or meat by-product

(a) at all times
  (i) has a temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher, or
28-4-77 (ii) has been stored at an ambient temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher; and

23-6-88 (b) carries on the principal display panel of the label a statement to the effect that the food must be stored at a temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher.

*(R) Minor correction

Meat Product Extender

B.14.073. No person shall sell a meat product extender intended to be used in a food consisting of a mixture described in section B.14.074, B.14.075, B.14.076, B.14.077 or B.14.078, unless that extender

(a) has, in the rehydrated state,

28-1-75 (i) a total protein content of not less than 16 per cent; and

5-8-82 (ii) a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(b) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively, and

(c) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

Extended Meat Products

28-4-77 **B.14.074.** Subject to sections B.14.075 to B.14.079, no person shall sell a food that consists of a mixture of meat product and meat product extender, unless that food

(a) has a total protein content of not less than 16 per cent,

5-8-82 (b) has a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

10-8-77 (c) in respect of the meat product extender, meets the requirements of paragraphs B.14.073 (a) to (c).

20-1-75 **B.14.075.** No person shall sell a food that consists of a mixture of meat product and meat product extender and that resembles fresh sausage, unless that food

(a) has a total protein content of not less than 9 per cent,

(b) has a fat content of not more than 40 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

5-8-82 10-8-77 (c) in respect of the meat product extender, meets the requirements of paragraphs B.14.073 (a) to (c).

28-1-75 **B.14.076.** No person shall sell a food that consists of a mixture of meat product and meat product extender and that resembles cooked sausage, meat loaf, meat by-product loaf, meat roll, meat lunch, or luncheon meat, unless that food

(a) has a total protein content of not less than 11 per cent,

5-8-82 (b) has a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

28-1-75 (c) in respect of the meat product extender, meets the requirements of paragraphs B.14.073 (a) to (c).

12-4-84 **B.14.077.** No person shall sell a food that consists of a mixture of meat product and meat product extender and that resembles potted meat, potted meat by-product, meat paste, meat by-product paste, meat spread, or meat by-product spread, unless that food

(a) has a total protein content of not less than 9 per cent,

5-8-82 (b) has a fat content of not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

28-1-75 (c) in respect of the meat product extender, meets the requirements of paragraphs B.14.073 (a) to (c).

*(R) Minor correction

B.14.078. No person shall sell a food that consists of a mixture of meat product and meat product extender and that resembles regular ground beef, medium ground beef or lean ground beef, unless that food

28-4-77 (a) has a total protein content of not less than 16 per cent;

(b) has a fat content of

(i) not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being regular,

(ii) not more than 23 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being medium, or

5-8-82 (iii) not more than 17 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being lean; and

28-4-77 (c) in respect of the meat product extender, meets the requirements of paragraphs B.14.073(a) to (c).

B.14.079. No person shall sell a food that consists of a mixture of meat product, filler and meat product extender, unless that food

28-4-77 (a) has a total protein content of not less than 13 per cent;

5-8-82 (b) has a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

10-8-77 (c) in respect of the meat product extender, meets the requirements of paragraphs B.14.073(a) to (c).

Simulated Meat Products

B.14.085. Subject to sections B.14.086 to B.14.090 no person shall sell a simulated meat product, unless that product

10-8-77 (a) has, in the rehydrated state,

(i) a total protein content of not less than 16 per cent,

(ii) a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981, and

5-8-82 (iii) a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;

(b) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively, and

10-8-77 (c) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

10-8-77 **B.14.086.** No person shall sell a simulated meat product that resembles fresh sausage, unless that product

(a) has a total protein content of not less than 9 per cent,

5-8-82 (b) has a protein rating of not less than 23, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(c) has a fat content of not more than 40 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;

10-8-77 (d) has, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively, and

28-1-75 (e) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

10-8-77 **B.14.087.** No person shall sell a simulated meat product that resembles cooked sausage, meat loaf, meat by-product loaf, meat roll, meat lunch, or luncheon meat, unless that product

(a) has a total protein content of not less than 11 per cent,

5-8-82 (b) has a protein rating of not less than 28, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(c) has a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;

(d) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively, and

28-1-75 (e) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

10-8-77 **B.14.088.** No person shall sell a simulated meat product that resembles potted meat, potted meat by-product, meat paste, meat by-product paste, meat spread, or meat by-product spread, unless that product

(a) has a total protein content of not less than 9 per cent,

5-8-82 (b) has a protein rating of not less than 23, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(c) has a fat content of not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;

28-1-75 (d) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively, and

(e) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

28-4-77 **B.14.089.** No person shall sell a simulated meat product that resembles regular ground beef, medium ground beef or lean ground beef, unless that product

(a) has a total protein content of not less than 16 per cent;

(b) has a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(c) has a fat content of

(i) not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being regular,

5-8-82 (ii) not more than 23 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being medium, or

(iii) not more than 17 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being lean;

28-4-77 (d) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in column I of the Table to this Division in an amount not less than the amount shown in column II of that Table opposite each such vitamin and mineral nutrient, respectively; and

(e) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

28-1-75 **B.14.090.** No person shall sell a simulated meat product that resembles side bacon, unless that product

(a) has a total protein content of not less than 25 per cent,

5-8-82 (b) has a protein rating of not less than 20, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981,

(c) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively, and

28-1-75 (d) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

TABLE

Item No.	*Column I* *Vitamin or Mineral Nutrient*	*Column II* *Amount per gram of protein*
C.1	Copper	4.4 micrograms
F.1	Folic Acid	0.45 microgram
I.1	Iron	0.25 milligram
M.1	Magnesium	1.1 milligrams
N.1	Niacin	0.34 milligram
P.1	Pantothenic Acid	0.04 milligram
P.2	Potassium	20.0 milligrams
P.3	Pyridoxine	0.02 milligram
R.1	Riboflavin	0.01 milligram
T.1	Thiamine	0.02 milligram
V.1	Vitamin B_{12}	0.08 microgram
Z.1	Zinc	0.20 milligram

Adulteration of food

B.15.001. A food named in column III of an item of Table I to this Division is adulterated if the substance named in Column I of that item is present therein or has been added thereto in an amount exceeding the amount, expressed in parts per million, shown in column II of that item for that food.

22-1-81 **B.15.002.** (1) Subject to subsections (2) and (3), a food is adulterated if an agricultural chemical or any of its derivatives is present therein or has been added thereto, singly or in any combination, in an amount exceeding 0.1 part per million, unless it is listed and used in accordance with the tables to Division 16.

(2) Subject to subsection (3), a food is exempt from paragraph 4(d) of the Act if the only agricultural chemicals that are present therein or have been added thereto are any of the following:

(a) a fertilizer;
(b) an adjuvant or a carrier of an agricultural chemical;
(c) an inorganic bromide salt;
(d) silicon dioxide;
22-3-05 (e) sulphur;
(f) viable spores of Bacillus thuringiensis Berliner; or
(g) kaolin.

26-1-98 (3) A food named in column IV of an item of Table II to this Division, a food that contains any such food or a food made from a product of any such food is exempt from the application of paragraph 4(d) of the Act if the agricultural chemicals named in columns I and II of that item are present in or have been added to the food in an amount not exceeding the maximum residue limit set out in column III of that item.

3-7-97 (4) A food set out in a Notice of Interim Marketing Authorization published under subsection B.01.056(6) is exempt from paragraph 4(d) of the Act in respect of any agricultural chemical or derivative of such a chemical, and any veterinary drug, set out in that notice that is present in the food in an amount not exceeding the maximum residue limit, expressed in parts per million, set out for the food in that notice.

11-4-91 **B.15.003.** A food named in column IV of an item of Table III to this Division is exempt from paragraph 4(d) of the Act if the drug named in column I, and analysed as being the substance named in column II, of that item is present in the food in an amount not exceeding the limit, expressed in parts per million, set out in column III of that item for that food.

TABLE I

Item No.	I Substance	II Tolerance p.p.m.	III Foods
4-5-89 1.	Arsenic	(1) 3.5 (2) 1 (3) 0.1	(1) Fish protein (2) Edible bone meal (3) Fruit juice, fruit nectar, beverages when ready-to-serve and water in sealed containers other than mineral water or spring water
8-3-79 2.	Fluoride	(1) 650 (2) 150	(1) Edible bone meal (2) Fish Protein
3.	Lead	(1) 10 (2) 1.5 (3) 0.5 (4) 0.2 (5) 0.15 (6) 0.08	(1) Edible bone meal (2) Tomato paste and tomato sauce (3) Fish protein and whole tomatoes (4) Fruit juice, fruit nectar, beverages when ready-to-serve and water in sealed containers other than mineral water or spring water (5) Evaporated milk, condensed milk and concentrated infant formula (6) Infant formula when ready-to-serve
14-2-91			
4.	Tin	(1) 250	(1) Canned foods

*(R) Minor correction

TABLE II
AGRICULTURAL CHEMICALS

21-10-99	I Item No.	I Common Chemical Name	II Chemical Name of Substance	III Maximum Residue Limit p.p.m.	IV Foods
30-1-01	A.0001	abamectin	(10*E*,14*E*,16*E*,22*Z*)-(1*R*,4*S*,5'*S*,6*S*,6'*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-6'-[(*S*)-*sec*-butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.1^{4,8}.0^{20,24}]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'*H*-pyran)-12-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)-3-*O*-methyl-α-L-*arabino*-hexopyranoside (avermectin B_{1a}) (10*E*,14*E*,16*E*,22*Z*)-(1*R*,4*S*,5'*S*,6*S*,6'*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.1^{4,8}.0^{20,24}]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'*H*-pyran)-12-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)-3-*O*-methyl-α-L-*arabino*-hexopyranoside (avermectin B_{1b}) A mixture of avermectin B_{1a} and B_{1b}, and their 8,9-Z isomers, in the ratio of 80 to 20 respectively.	0.05 0.02 0.01 0.005	Celery, head lettuce Apples, citrus fruits, pears, strawberries Peppers, tomatoes Almonds, cucumbers, walnuts
23-5-02 8-4-97 23-11-95	A.001	acephate	*O*,*S*-dimethyl acetyl phosphoramidothioate	5.0 2.0 1.5 1.0 0.5 0.3 0.05	Celery Cauliflower, peppers Brussels sprouts Lettuce, beans Corn, cranberries, potatoes, soybeans Cabbage Milk
21-10-99 31-1-91	A.01	alachlor	2-chloro-2',6'-diethyl-N-methoxy-methylacetanilide including the metabolites containing the diethylaniline or 2-ethyl-6-(1-hydroxyethyl) aniline moieties	0.2 0.02 0.001	Soybeans Corn, dry beans, soybean oil Meat, milk

*(R) Minor correction

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
21-10-99 23-5-02 3-2-77	A.02	aldicarb	2-methyl-2-(methylthio) propionaldehyde-*O*-(methylcarbamoyl) oxime, including the metabolites aldicarb sulfoxide and aldicarb sulfone	0.5	Potatoes
8-3-79 17-11-77	A.1	aldrin and dieldrin	1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-1,4-endo,exo-5,8-dimethanonaphthalene and	0.2 (calculated on the fat content)	Meat, meat by-products and fat of cattle, goats, hogs, poultry and sheep.
27-4-78			1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4-endo,exo-5,8-dimethanonaphthalene	0.1 (calculated on the fat content)	Butter, cheese, milk and other dairy products.
23-5-02 26-5-94	A.1.1	amitraz	N,N-bis(2,4-xylyliminomethyl) methylamine, including the metabolite N-(2,4-dimethylphenyl)-N'-methyl formamidine	1.0 0.5 0.2	Pears Apples Liver and kidney of cattle and hogs
25-10-01	A.1.2	amitrole	3-amino-*s*-triazole	0.01	Barley, peas, rapeseed (canola), wheat
23-5-02 21-10-99 8-3-79	A.2	anilazine	2,4-dichloro-6-(2-chloroanilino)-1,3,5-triazine	20 10 5 1	Strawberries. Blueberries, celery, cranberries, currants, garlic, gooseberries, leeks, onions, shallots, tomatoes. Blackberries, cucumbers, dewberries, loganberries, melons, pumpkins, raspberries, squash. Potatoes
21-10-99 27-4-78 23-5-02 13-9-79	A.3	azinphos-methyl	S-(3,4-dihydro-4-oxobenzo [d]-[1,2,3] triazin-3-ylmethyl)*0,0*-dimethyl phosphorodithiate	5.0 2.0 1.0 0.5 0.4 0.2	Grapes. Apples, apricots, beans, blackberries, blueberries, boysenberries, citrus fruits, loganberries, peaches/nectarines, pears, quinces, raspberries, spinach. Broccoli, Brussels sprouts, cabbage, cherries, cranberries, currants, onions (green), plums, tomatoes, strawberries. Artichokes, cauliflower, celery, cucumbers, onions (dry bulb). Kiwi fruit (edible portion). Peppers.

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
31-1-02	A.4	azoxystrobin	(α*E*)-methyl 2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-α-(methoxymethylene) benzeneacetate, including the isomer (*Z*)-methyl 2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]--(methoxymethylene) benzeneacetate	3 1 0.8 0.6 0.3 0.2 0.06 0.03 0.01	Grapes Bananas, rapeseed (canola) Peaches/nectarines Tomato paste Liver of cattle, hogs, horses and sheep Tomatoes Kidney of cattle, hogs, horses and sheep Peanut oil Meat and meat by-products of cattle, hogs, horses and sheep, peanuts, pecans
23-5-02 8-3-79	B.	benomyl, carbendazim and thiophanate-methyl	methyl 1-(butylcarbamoyl) benzimidazol-2-ylcarbamate, methyl benzimidazol-2-ylcarbamate (carbendazim), and 1,2-di-(3-methoxy-carbonyl-2-thioureido)-benzene, expressed as carbendazim	10 6 5 2.5 1 0.5	Citrus fruits, peaches/nectarines. Blackberries, boysenberries, raspberries. Apples, apricots, carrots, cherries, grapes, mushrooms, pears, plums, strawberries. Tomatoes. Beans, pineapples (edible pulp). Cucumbers, melons, pumpkins, squash.
25-10-01 26-10-04	B.01	bentazon	3-(1-methylethyl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide, including the metabolites 6-hydroxy-3-(1-methylethyl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide and 8-hydroxy-3-(1-methylethyl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide	3 0.5 0.1 0.05	Peas Beans Barley, leeks, onions, wheat Blueberries, corn, flax, peanuts, rice, soybeans
8-3-79	B.1	BHC isomers, except lindane	all isomers of 1,2,3,4,5,6-hexachloro-cyclohexane, except gamma BHC	0.1 (calculated on the fat content)	Butter, cheese, milk and other dairy products; meat and meat by-products of cattle, goats, hogs, poultry and sheep.
4-3-75	B.2	biphenyl	biphenyl	110	Citrus fruits.
4-3-75 23-5-02	B.4	bromophos	*O*-(4-bromo-2,5-dichlorophenyl), *O*-*O*-dimethyl phosphorothioate	1.5	Apples.
23-6-99	B.5	bromopropylate	isopropyl 4,4'-dibromobenzilate	2 10	Citrus fruits, grapes Raisins
20-9-01	B.6	bromoxynil	3,5-dibromo-4-hydroxybenzonitrile, including the metabolite 3,5-dibromo-4-hydroxybenzoic acid	0.1	Eggs, meat and meat by-products of cattle and poultry, milk, rapeseed (canola)

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
23-5-02 24-3-83	C.2	captan	3a,4,7,7a-tetrahydro-*N*-(trichloromethane-sulphenyl)-phthalimide	5.0	Apples, apricots, blueberries, cranberries, cherries, grapes, peaches/nectarines, pears, plums, raspberries, strawberries, tomatoes.
28-8-76	C.3	carbaryl	1-naphthyl-methylcarbamate	10	Apricots, asparagus, beet tops, blackberries, boysenberries, cherries, Chinese cabbage, citrus fruits, collards, cranberries, dandelions, dewberries, endives, kale, lettuce, loganberries, mustard greens, nuts (whole in shells), okra, olives (raw), parsley, peaches/nectarines, plums, raspberries, salsify tops, spinach, Swiss chard, turnip tops, watercress.
23-5-02				7	Blueberries, strawberries.
25-8-76				5	Apples, bananas, beans, beet roots, broccoli, Brussels sprouts, cabbages, carrots, cauliflower, celery, eggplants, grapes, horseradish, kohlrabi, parsnips, pears, peas, peppers, poultry meat, radishes, salsify roots, tomatoes, turnip roots.
				3	Cucumbers, melons, pumpkins, squash.
				2	Barley, oats, rye, wheat.
				1	Corn, nuts (shelled).
				0.2	Potatoes.
21-10-99	C.4	carbofuran	2,3-dihydro-2,2-dimethyl-7-benzofuranyl methylcarbamate	0.5	Carrots, peppers, potatoes, rutabagas (turnips).
				0.4	Strawberries.
13-5-75			including the metabolite 3-hydroxy carbofuran	0.3	Onions.
8-3-79 27-4-78	C.4.1	carbofuran phenolic metabolites	2,3-dihydro-2,2-dimethyl-7-hydroxybenzofuran,2,3-dihydro-2,2-dimethyl-7-hydroxy-3-oxobenzofuran and	1.0	Carrots, potatoes, turnips.
			2,3-dihydro-2,2-dimethyl 3,7-dihydroxybenzofuran	0.5	Onions, peppers, strawberries.
8-3-79 27-4-78	C.6	chlordane	1,2,4,5,6,7,8,8-octachloro-3a,4,7,7a-tetrahydro-4,7-methanoindan including the metabolite oxychlordane	0.1 (Calculated on the fat content)	Butter, cheese, milk and other dairy products; meat and meat by-products of cattle, goats, hogs, poultry and sheep.

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99 Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
5-4-05	C.6.1 chlorimuron-ethyl	ethyl 2-[[[[(4-chloro-6-methoxy-2-pyrimidinyl)amino] carbonyl]amino]sulfonyl] benzoate	0.05	Soybeans
21-10-99	C.7 chlormequat	(2-chloroethyl) trimethyl ammonium ion	1.0	Wheat.
21-10-99	C.7.1 chlorthal-dimethyl	dimethyl tetrachloroterephthalate	5 2	Mustard greens, turnip greens. Beans, black-eyed peas, collards, kale, lettuce, peppers, pimentos, potatoes, soybeans, strawberries, sweet potatoes, turnips, yams.
13-9-79			1	Broccoli, Brussels sprouts, cabbage, cantaloupes, cauliflower, cucumbers, eggplants, garlic, honeydew melons, onions, summer squash, tomatoes, watermelons, winter squash.
23-5-02	C.9 chlorothalonil	tetrachloro-isophthalonitrile, including the metabolite 4-hydroxy-2,5,6-trichloro-1,3-benzenedicarbonitrile	15	Celery
8-4-97 14-12-94 13-4-00			5	Beans, broccoli, Brussels sprouts, cabbage, cauliflower, cucumbers, melons, onions, pumpkins, squash, tomatoes, wasabi
			2	Cranberries
			1	Carrots, mushrooms, parsnips
			0.6	Blueberries
			0.5	Cherries, peaches/nectarines
			0.3	Peanuts
21-10-99	C.10 chlorpropham	isopropyl 3-chlorophenylcarbamate	15.0	Potatoes
31-8-05 23-5-02 28-7-99	C.10.1 chlorpyrifos	*O,O*-diethyl-*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate	0.01	Apples, grapes, tomatoes
		O,O-diethyl-*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate, including the metabolite 3,5,6-trichloro-2-pyridinol	2	Kiwi fruit
9-8-78			1 (calculated on the fat content)	Meat and meat by-products of cattle
2-6-94			1	Citrus fruits; fat, kidney and liver of cattle; peppers
			0.5	Rutabagas

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
20-9-01	C.10.1.1	clethodim	(*E,E*)-(±)-2-[1-[[-3-chloro-2-propenyl)oxy]imino]	10	Soybeans
23-6-99			propyl]-5-[2-(ethylthio) propyl]-3-hydroxy-2-cyclohexen-1-one, including metabolites containing the 2-cyclohex-1-enone moiety	0.5 0.4 0.3 0.2 0.05	Beans, chickpeas, lentils, peas (dry), potatoes Mustard seed Flaxseed Onions, sunflower (including sunola) seeds Rapeseed (canola)
23-5-02	C.10.2	clofentezine	3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine	0.5 1.0	Almonds, apples, pears Peaches/nectarines
21-10-99			3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine including the metabolite 3-(2-chloro-4-hydroxyphenyl)-6-(2-chlorophenyl)-1,2,4,5-tetrazine	0.01 0.05	Milk Meat and meat by-products (except liver) of cattle, goats, hogs, horses and sheep
25-5-93	C.10.3	clomazone	2-(2-cholorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one	0.05	Soybeans.
5-4-05	C.10.4	clopyralid	3,6-dichloro-2-pyridinecarboxylic acid	7	Barley, oats and wheat milling fractions, excluding flour
13-4-00				2 1 0.36 0.2 0.05 0.01	Barley, oats, wheat Broccoli, cabbage, cauliflower, Chinese broccoli, Chinese mustard cabbage, kohlrabi, Napa Chinese cabbage, strawberries Kidney of cattle, goats, horses and sheep Flax, kidney of poultry Eggs; fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep; kidney of hogs Milk
30-5-02	C.10.5	cloransulam-methyl	methyl 3-chloro-2-[[(5-ethoxy-7-fluoro[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)sulfonyl]amino] benzoate, including the metabolite 3-chloro-2-[[(5-ethoxy-7-fluoro[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)sulfonyl]amino] benzoic acid, calculated as ester	0.01	Soybeans

*(R) Minor correction

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
	Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
21-10-99	C.10.6	clothianidin	[C(*E*)]-*N*-[(2-chloro-5-thiazolyl)methyl]-*N'*-methyl-*N''*-nitroguanidine	0.01	Field corn grain, milk, popcorn grain, rapeseed (canola), sweet corn kernel plus cob with husks removed
21-10-99	C.11	copper compounds	copper compounds (inorganic) including copper oxychloride, copper oxychloride-sulphate, copper sulphate, copper sulphate monohydrate, tribasic copper sulphate	50.0 (calculated as copper)	Fresh fruits and vegetables.
21-10-99	C.12	coumaphos	*O*-3-chloro-4-methylcoumarin-7-yl *O,O*-diethyl phosphorothioate	0.5 (calculated on the fat content)	Meat, meat by-products and fat of cattle, goats, horses, hogs, poultry and sheep.
13-9-79	C.13	4-CPA	(*p*-chlorophenoxy) acetic acid	2.0	Mung bean sprouts
13-4-00	C.13.01	cyfluthrin	(*RS*)-α-cyano-4-fluoro-3-phenoxybenzyl(1*RS*, 3*RS*)-(1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate	15 5 0.5 0.4 0.01	Milk fat (in whole milk) Fat of cattle, goats, hogs, horses, poultry and sheep Milk Meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep Eggs
8-5-03 20-11-97	C.13.1	cyhalothrin-lambda	[1α(*S**),3α(*Z*)](±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane-carboxylate	2 1 (calculated on the fat content) 0.4 0.3 0.2	Head lettuce Milk Broccoli, cabbage Sunflower oil Meat of cattle, goats, hogs, horses and sheep, sunflower seeds
16-11-04				0.15 0.1 0.05	Corn flour, leeks Tomatoes Corn

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
25-10-01	C.14	cymoxanil	2-cyano-*N*-[(ethylamino) carbonyl]-2-(methoxyimino) acetamide	0.05	Fat, meat and meat by-products of cattle, goats, hogs and sheep, milk, potatoes
23-5-02	C.16	cypermethrin	(RS)-α-cyano-3-phenoxybenzyl (1RS, 3RS)-(1RS, 3SR)-3- (2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate	1.0	Apples, celery, citrus fruits.
21-10-99				0.5	Beans, broccoli, Brussels sprouts, cabbage, cauliflower, grapes, pears.
				0.3	Tomatoes.
				0.2	Peaches/nectarines, strawberries.
23-6-99	C.16.1	cyprodinil	4-cyclopropyl-6-methyl-N-phenylpyrimidin-2-amine	3	Raisins
				2	Grapes, stone fruit
				0.1	Pome fruit
				0.02	Almonds
28-8-97	C.17	cyromazine	N-cyclopropyl-1,3,5-triazine-2,4,6-triamine, including the metabolite 1,3,5-triazine-2,4,6-triamine	10.0	Celery, leaf lettuce, spinach
				8.0	Mushrooms
				4.0	Head lettuce
				3.0	Onions (green), peppers
				1.5	Dry potato products
				1.0	Cucumbers, melons, tomatoes
				0.5	Potatoes
				0.3	Onions (dry)
13-4-00	D.1	2,4-D	(2,4-dichlorophenoxy) acetic acid	5	Asparagus
				2	Citrus fruits
				0.5	Cranberries
5-4-05	D.2.1	daminozide	succinic acid mono(2,2-dimethylhydrazide), including the metabolite 1,1-dimethylhydrazine	0.02	All food crops
	D.3	DDT	1,1,1-trichloro-2,2-bis(chlorophenyl) ethane including the metabolites 1,1-dichloro-2,2-bis (p-chlorophenyl) ethane (TDE or DDD) and 1,1-dichloro-2,2-bis(p-chlorophenyl) ethylene (DDE)	5.0	Fish.
29-7-82				1.0 (calculated on the fat content)	Butter, cheese, milk and other dairy products; meat, meat by-products and fat of cattle, hogs, poultry and sheep.
				0.5	Eggs, fresh vegetables.

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
23-5-02 13-4-00	D.7	diazinon	*O,O* diethyl-*O*-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate	0.75	Apples, apricots, beets, broccoli, cabbage, carrots, cauliflower, celery, cherries, endives, grapes, kale, kohlrabi, lettuce, onions, pears, peppers, plums, salsify, spinach, strawberries, tomatoes, turnip tops, wasabi
				0.7	Citrus fruits, peaches/nectarines
				0.5	Beans, Brussels sprouts, cucumbers, turnips
				0.25	Cantaloupes, collards, cranberries, figs, hops, lima beans, muskmelons, parsley, parsnips, radishes, summer squash, Swiss chard, watermelons, winter squash
23-5-02 21-10-99	D.9	dichlone	2,3-dichloro-1,4-naphthoquinone	3	Apples, cherries, peaches/nectarines, plums, prunes.
				15	Strawberries.
23-5-02 21-10-99	D.10	dichloran	2,6-dichloro-4-nitroaniline	20	Snap beans
				15	Peaches/nectarines, sweet cherries
15-11-84				10	Apricots, blackberries, celery, grapes, lettuce, raspberries, strawberries
				5	Carrots, onions, plums, rhubarb, sweet potatoes, tomatoes.
				0.5	Cucumbers, garlic
4-3-75	D.11	dichlorvos	2,2-dichlorovinyl dimethyl phosphate	0.25	Tomatoes.
				0.50	Non-perishable packaged foods of low fat content (under 6%).
				2.0	Non-perishable packaged foods of high fat content (over 6%).

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
23-5-02 21-10-99 13-9-79 27-4-78	D.12	dicofol	1,1-bis(*p*-chlorophenyl) 2,2,2-trichloroethanol	5.0 3.0 0.1 (calculated on the fat content)	Citrus fruits. Almonds, apples, apricots, beans, blackberries, boysenberries, cantaloupes, cherries, chestnuts, cucumbers, dewberries, eggplants, figs, filberts, grapes, hickory nuts, honeydew melons, loganberries, muskmelons, peaches/ nectarines, pears, peas, pecans, peppers, pimentos, plums, pumpkins, quinces, raspberries, soybeans, strawberries, summer squash, tomatoes, walnuts, watermelons, winter squash. Butter, cheese, milk and other dairy products, meat and meat by-products of cattle, goats, hogs, poultry and sheep.
17-11-77	D.13	dieldrin see aldrin			
5-4-05 23-3-04	D.14	difenoconazole	1-[2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole	0.1 0.05 0.03 0.01	Wheat Eggs; meat and meat by-products of cattle, goats, hogs, poultry and sheep; mustard seed Rapeseed (canola) Barley, field corn grain, milk, sweet corn kernel plus cob with husks removed
18-5-00	D.14.1	diflufenzopyr	2-[1-[[[(3,5-difluorophenyl)amino] carbonyl]hydrazono] ethyl]-3-pyridinecarboxylic acid including its metabolites convertible to M1 (8-methyl-5(6H)-pyrido [2,3-d] pyridazinone)	0.05	Corn
5-4-05	D.14.2	dimethenamid	2-chloro-*N*-(2,4-dimethyl-3-thienyl)-*N*-(2-methoxy-1-methylethyl) acetamide	0.01	Onions (dry bulb)
23-5-02 11-10-84	D.15	dimethoate	*O,O*-dimethyl **S**-(**N**-methylcarbamoyl-methyl) phosphorodithioate including the metabolite omethoate	2.0 1.5 1.0 0.5	Apples, beet greens, broccoli, cabbages, cauliflower, cherries, kale, lettuce, pears, spinach, Swiss chard, turnip greens. Citrus fruits. Beans, blueberries, celery, strawberries. Peas, peppers, tomatoes.

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
5-4-05	D.16	dimethomorph	(*E,Z*)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine	0.01	Potatoes
4-3-75	D.17	diphenamid	N,N-dimethyl-2,2-diphenylacetamide	1	Strawberries.
15-11-84	D.18	diphenylamine	diphenylamine	5.0	Apples.
23-6-99	D.18.1	diquat	9,10-dihydro-8a, 10a-diazonia-phenanthrene ion	0.5	Flax, solin
8-4-97				0.2	Lentils
				0.05	Eggs, meat and meat by-products, milk, poultry meat and poultry meat by-products
23-5-02	D.19	disulfoton	*O,O*-diethyl S-[2-(ethylthio)ethyl] phosphorodithioate	0.2	Potatoes.
21-10-99				0.5	Beans, broccoli, Brussels sprouts, cabbage, cauliflower, lettuce, peas, spinach, tomatoes.
4-3-75					
23-5-02	D.21	diuron	3-(3,4-dichlorophenyl)-1,1-dimethylurea	1	Citrus fruits, corn, grapes, pineapples, potatoes, wheat.
21-10-99					
4-3-75				7	Asparagus.
27-4-78	D.22	dodine	N-dodecylguanidine acetate	5.0	Apples, pears, strawberries.
				2.0	Cherries.
21-10-99	E.1	endosulfan	6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin 3-oxide, including the metabolite endosulfan sulfate	2.0	Apples, apricots, broccoli, Brussels sprouts, cabbage, cherries, lettuce, peaches/nectarines, pears, plums, spinach.
23-5-02					
27-4-78					
				1.0	Artichokes, beans, cauliflower, celery, cucumbers, eggplants, grapes, melons, peppers, pumpkins, squash, strawberries, tomatoes, watercress.
13-9-79				0.5	Peas.
				0.1 (calculated on the fat content)	Butter, cheese, milk and other dairy products; meat and meat by-products of cattle, goats, hogs, poultry and sheep.
	E.1.1	endrin	1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-endo-endo-1,4:5,8-dimethanonaphthalene	0.02 (calculated on the fat content)	Butter, cheese, milk and other dairy products.
13-9-79					
27-4-78					

TABLE II (continued)
AGRICULTURAL CHEMICALS

21-10-99	*I* *Item No.*	*I* *Common Chemical Name*	*II* *Chemical Name of Substance*	*III* *Maximum Residue Limit p.p.m.*	*IV* *Foods*
21-10-99	E.2	ethephon	2-chloroethyl phosphonic acid	20	Blackberries
				10	Blueberries
				8	Sweet cherries
				5	Raisins
				3	Apples, figs, peppers
21-10-99				2	Barley and wheat milling fractions, excluding flour, cranberries, sour cherries, tomatoes
				1	Citrus fruits, grapes
				0.5	Barley, cantaloupes, pineapples, wheat
23-5-02 27-4-78	E.3	ethion	*O,O,O',O'*-tetraethyl S,S'-methylene-bisphosphorodithioate	2.5 (calculated on the fat content)	Meat, meat by-products and fat of cattle.
				2.0	Apples, citrus fruits, grapes, pears.
23-5-02 13-9-79				1.0	Beans, peaches/nectarines, plums, strawberries.
				0.5	Tomatoes.
21-10-99 23-5-02	E.4	ethoxyquin	1,2-dihydro-6-ethoxy-2,-2,4-trimethyl-quinoline polymer	0.5 3	Eggs, meat, poultry meat. Apples, pears, poultry fat, liver of poultry.
24-10-02 14-6-01	E.5	ethylenebis-dithiocarbamate fungicides	manganese and zinc ethylenebis (dithiocarbamate) (polymeric)	7	Apples, broccoli, Brussels sprouts, cabbage, cauliflower, eggplants, endives, grapes, lettuce, mushrooms, onions (green), pears, peppers
				6	Lentils
				5	Celery
				4	Cucumbers, tomatoes
				0.5	Onions (dry)
5-4-05	F.01	famoxadone	5-methyl-5-(4-phenoxyphenyl)-3-(phenylamino)-2,4-oxazolidinedione	1.0	Tomatoes
				0.06	Milk fat
				0.05	Liver of cattle, goats, horses and sheep
				0.02	Fat of cattle, goats, horses and sheep; potatoes
5-4-05	F.02	fenamidone	(5*S*)-3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-4*H*-imidazol-4-one	0.02	Potatoes

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
5-4-05	F.03	fenbuconazole	α-[2-(4-chlorophenyl)ethyl]-α-phenyl-1*H*-1,2,4-triazole-1-propanenitrile, including the metabolites *cis*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)-2-3*H*-furanone	0.8 0.5 0.3 0.1	Sour cherries, sweet cherries Dried prune plums, peaches/nectarines Apricots Plums, prune plums
21-10-99	F.1	fenbutatin oxide	di [tri-(2-methyl-2-phenylpropyl)tin] oxide	3.0 2.0 0.5	Apples, pears. Citrus fruits. Cucumbers, tomatoes.
1-5-03 25-10-01 30-1-01	F.1.001	fenhexamid	*N*-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexane carboxamide	20 6 4 3 0.5 0.02	Blackberries, loganberries, raspberries Apricots, cherries, peaches/nectarines, raisins Grapes Strawberries Plums Almonds
11-1-95	F.1.01	fenoxaprop-ethyl	(RS)-ethyl-2-[4-(6-chloro-1,3-benzoxazol-2-yloxy)-phenoxy]propanoate including the metabolites 2-[4-[(6-chloro-2-benzoxazolyl)-oxy]phenoxy]propionic acid and 6-chloro-2,3-dihydrobenzoxalazol-2-one	0.02	Milk

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
	F.1.1	ferbam	ferric dimethyldithiocarbamate	7 (calculated as zineb)	Apples, apricots, asparagus, beans, beets, blackberries, black-eyed peas, blueberries, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, celery, cherries, collards, corn, cranberries, cucumbers, currants, dates, eggplants, gooseberries, grapes, guavas, huckleberries, kale, kohlrabi, lettuce, loganberries, mangoes, melons, mustard greens, onions, papayas, peaches/nectarines, peanuts, pears, peas, peppers, plums, (fresh prunes), pumpkins, quinces, radishes, raspberries, rutabagas, spinach, squash, strawberries, summer squash, tomatoes, turnips.
13-9-79 23-5-02					
7-11-02	F.1.1.01	florasulam	*N*-(2,6-difluorophenyl)-8-fluoro-5-methoxy[1,2,4]triazolo [1,5-c]pyrimidine-2-sulphonamide	0.01	Barley, oats, wheat
16-11-04	F.1.1.1	fluazifop-butyl	butyl(±)-2-[4-[[5-(trifluoromethyl-2-pyridinyl]oxy] phenoxy]propanoate	1 (calculated as acid) 0.3 (calculated as acid) 0.2 (calculated as acid) 0.1 (calculated as acid) 0.05 (calculated as acid) 0.01 (calculated as acid)	Soybeans, strawberries Mustard Flax, solin Blueberries Eggs; fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep Milk
13-9-00 29-10-98	F.1.1.2	fluazuron	1-[4-chloro-3-(3-chloro-5-trifluoromethyl-2-pyridyloxy)phenyl]-3-(2,6-difluorobenzoyl) urea	7.0 0.5	Fat of cattle Meat by-products of cattle

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
20-9-01	F.1.1.3	flucarbazone-sodium	4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2-(trifluoromethoxy) phenyl]sulfonyl]-1*H*-1,2,4-triazole-1-carboxamide, sodium salt, including the metabolite 4,5-dihydro-3-methoxy-5-oxo-*N*-[[2-(trifluoromethoxy)phenyl] sulfonyl]-1*H*-1,2,4-triazole-1-carboxamide, sodium salt	0.01	Wheat
14-1-88 6-4-89	F.1.2	flucythrinate	(RS)-α-cyano-3-phenoxybenzyl (S)-2-(4-difluoromethoxyphenyl)-3-methylbutyrate	0.1 (calculated on the fat content)	Milk
16-11-04 24-10-02 20-9-01	F.1.2.1	fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl) 1*H*-pyrrole-3-carbonitrile	7 2 1 0.2 0.05 0.02 0.01	Onions (green) Apricots, peaches/nectarines, plums, strawberries Grapes Onions (dry bulb) Fat, kidney and liver of cattle, goats, hogs, horses and sheep; mustard Potatoes Meat of cattle, goats, hogs, horses and sheep; milk; rapeseed (canola)
13-9-00	F.1.3	flusilazole	bis(4-fluorophenyl)(methyl)(1*H*-1,2,4-triazole-1-ylmethyl)silane	1 0.5 0.2 0.1 0.01*	Raisins Grapes Apples Bananas Meat and meat by-products of cattle; milk
23-5-02 21-10-99	F.2	folpet	*N*-(trichloromethylthio) phthalimide	30 25 15	Celery Apples, avocados, blackberries, blueberries, boysenberries, cherries, crabapples, cranberries, currants, dewberries, gooseberries, grapes, huckleberries, leeks, lettuce, loganberries, onions, raspberries, strawberries, tomatoes. Citrus fruits, cucumbers, garlic, melons, pumpkins, squash.
24-10-02 22-11-01	F.2.1	fomesafen	5-[2-chloro-4-(trifluoromethyl) phenoxy]-*N*-(methylsulfonyl)-2-nitrobenzamide	0.05	Dry beans, lima beans, snap beans, soybeans

* includes flusilazole, bis (4-fluorophenyl)(methyl)silanol and 1*H*-1,2,4-triazole

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
23-11-04	F.2.1.1	foramsulfuron	2-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbon yl]amino] sulfonyl]-4-(formylamino)-*N,N*-dimethylbenzamide	0.01	Field corn grain
21-10-99 23-5-02	F.3	formetanate hydrochloride	m-[[(dimethylamino) methylene] amino] phenyl methylcarbamate hydrochloride	4.0 3.0 0.5	Citrus fruits. Apples, peaches/nectarines, pears. Plums.
20-11-97 19-11-03 13-4-00	F.5	fosetyl-aluminum	aluminum tris(O-ethylphosphonate)	100 75 60 15 10 3 1 0.5	Celery, lettuce, spinach Strawberries Bok choy cabbage, broccoli, cabbage, cauliflower, Chinese broccoli, mustard greens Cantaloupes, cucumbers, squash Avocados Tomatoes Apples Onions (dry)
28-11-05 16-2-94	G.1	glufosinate-ammonium	ammonium(±)-2-amino-4-(hydroxymethyl-phosphinyl)butanoate, including the metabolite propanoic acid, 3-(hydroxymethyl-phosphinyl)	6 3.5 3 2 1 0.5 0.4 0.2 0.1 0.04	Lentils Cottonseed oil Dry peas, rapeseed (canola) Soybeans Liver and kidney of cattle, goats, hogs, poultry and sheep; rice Dry white beans Potatoes Corn, wheat Eggs; fat, meat and meat by-products of cattle, goats, hogs, poultry and sheep Milk
24-10-02 23-6-99 16-2-94 2-10-03 28-8-97	G.2	glyphosate	*N*-(phosphonomethyl) glycine, including the metabolite aminomethyl-phosphonic acid	35 20 15 10 5 4 3 2 0.5 0.2	Oat milling fractions, excluding flour Soybeans Barley and wheat milling fractions, excluding flour, oats Barley, rapeseed (canola), sugar beets Peas, wheat Beans, lentils Corn, flax Kidney of cattle, goats, hogs, poultry and sheep Asparagus Liver of cattle, goats, hogs, poultry and sheep
8-3-79	H.1	heptachlor	1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetra-hydro-4,7-methanoindene, including the metabolite heptachlor epoxide	0.2 (calculated on the fat content) 0.1 (calculated on the fat content)	Meat, meat by-products and fat of cattle, goats, hogs, poultry and sheep. Butter, cheese, milk and other dairy products.

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
21-10-99 4-3-75	H.2	hydrogen cyanide	hydrocyanic acid	25	Almonds, barley, cashew nuts, cocoa beans, corn, kidney beans, lima beans, navy beans, peanuts, pecans, rice, rye, walnuts, wheat.
28-8-01 21-10-99 21-6-84	I.1	iprodione	3-(3,5-dichlorophenyl)-**N**-isopropyl-2-4-dioxoimidazolidine-1 carboxamide including the metabolites 3-isopropyl-**N**-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide and 3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide	60 15 10 5 3 2 1 0.5 0.3	Raisins Lettuce Grapes, peaches/nectarines, raspberries Carrots, cherries, strawberries, wine Apricots Plums, prunes Rapeseed (canola) Cucumbers, kiwi fruit (edible portion), tomatoes Beans
23-5-02 5-5-83	I.2	imazalil	1-(β-allyloxy-2,4-dichlorophenethyl) imidazole	5.0	Citrus fruits
31-1-02	I.2.01	imazamox	2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-(methoxymetyl)-3-pyridinecarboxylic acid	0.1 0.05 0.01	Soybeans Peas, rapeseed (canola), wheat Eggs, meat and meat by-products of cattle, goats, horses, poultry and sheep, milk
28-6-05	I.2.02	imazethapyr	(±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-ethyl-3-pyridinecarboxylic acid, expressed as ammonium salt	0.1	Kidney beans, lima beans, navy beans, pinto beans, runner beans, snap beans, tepary beans, wax beans
5-4-05 29-5-03 20-9-01 23-6-99	I.2.1	imidacloprid	1-[(6-chloro-3-pyridinyl)methyl]-4,5-dihydro-*N*-nitro-1*H*-imidazol-2-amine, including metabolites containing the 6-chloropicolyl moiety	6 3.5 3 1.5 1 0.6 0.5 0.3 0.2 0.08 0.05	Tomato paste Brassica crops, lettuce Sour cherries, sweet cherries, tomato purée Grapes Blueberries, citrus fruits, peppers, tomatoes Pears Apples, cucumbers Potatoes Mangoes Eggplants Cottonseed oil, field corn grain, mustard seed, pecans, rapeseed (canola), sweet corn kernel plus cob with husks removed

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
21-10-99 4-3-75	H.2	hydrogen cyanide	hydrocyanic acid	25	Almonds, barley, cashew nuts, cocoa beans, corn, kidney beans, lima beans, navy beans, peanuts, pecans, rice, rye, walnuts, wheat.
28-8-01 21-10-99 21-6-84	I.1	iprodione	3-(3,5-dichlorophenyl)-**N**-isopropyl-2-4-dioxoimidazolidine-1 carboxamide including the metabolites 3-isopropyl-**N**-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide and 3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide	60 15 10 5 3 2 1 0.5 0.3	Raisins Lettuce Grapes, peaches/nectarines, raspberries Carrots, cherries, strawberries, wine Apricots Plums, prunes Rapeseed (canola) Cucumbers, kiwi fruit (edible portion), tomatoes Beans
23-5-02 5-5-83	I.2	imazalil	1-(β-allyloxy-2,4-dichlorophenethyl) imidazole	5.0	Citrus fruits
31-1-02	I.2.01	imazamox	2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-(methoxymetyl)-3-pyridinecarboxylic acid	0.1 0.05 0.01	Soybeans Peas, rapeseed (canola), wheat Eggs, meat and meat by-products of cattle, goats, horses, poultry and sheep, milk
28-6-05	I.2.02	imazethapyr	(±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-ethyl-3-pyridinecarboxylic acid, expressed as ammonium salt	0.1	Kidney beans, lima beans, navy beans, pinto beans, runner beans, snap beans, soybeans, tepary beans, wax beans
5-4-05 29-5-03 20-9-01 23-6-99	I.2.1	imidacloprid	1-[(6-chloro-3-pyridinyl)methyl]-4,5-dihydro-*N*-nitro-1*H*-imidazol-2-amine, including metabolites containing the 6-chloropicolyl moiety	6 3.5 3 1.5 1 0.6 0.5 0.3 0.2 0.08 0.05	Tomato paste Brassica crops, lettuce Sour cherries, sweet cherries, tomato purée Grapes Blueberries, citrus fruits, peppers, tomatoes Pears Apples, cucumbers Potatoes Mangoes Eggplants Cottonseed oil, field corn grain, mustard seed, pecans, rapeseed (canola), sweet corn kernel plus cob with husks removed

*(R) Minor correction

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
5-4-05	I.2.11	iodosulfuron-methyl-sodium	4-iodo-2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino] sulfonyl]benzoic acid methyl ester, monosodium salt	0.025	Field corn grain
22-3-05	I.2.2	iprovalicarb	[2-methyl-1[[[(1S)-(4-methylphenyl)ethyl] amino]carbonyl]propyl] carbamic acid methylethylester	2	Grapes
25-5-93	I.3	isofenphos	O-ethyl O-2-isopropoxy-carbonylphenyl isopropylphos-phoramidothioate including the metabolites 1-methylethyl-2-[[ethoxy[(1-methylethyl) amino] phosphinoxy]oxy] benzoate, 1-methylethyl-2-[[ethoxy(1-amino)phosphino-thioyl]oxy] benzoate and 1-methylethyl-2-[[ethoxy(1-amino) phosphinoxy]oxy] benzoate	0.01 0.02	Milk Eggs, rapeseed (canola)
22-3-05	I.3.1	isoxadifen-ethyl	ethyl 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylate	0.08	Field corn grain
25-10-01	I.4	isoxaflutole	(5-cyclopropyl-4-isoxazoly)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl] methanone, including the metabolite 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropylpropane, as parent equivalent	0.5 0.3 0.2 0.1 0.02 0.01	Liver of cattle Liver of poultry Meat of cattle, hogs, horses, poultry and sheep Meat by-products of cattle, hogs, horses, poultry and sheep Milk Eggs
			(5-cyclopropyl-4-isoxazoly)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl] methanone, including the metabolites 1-(2-methylsulfonyl-4-trifluorometylphenyl)-2-cyano-3-cyclopropylpropane and 2-metylslfonyl-4-trifluoromethyl benzoic acid, as parent equivalent	0.2	Corn

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
5-4-05	I.2.11	iodosulfuron-methyl-sodium	4-iodo-2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino] sulfonyl]benzoic acid methyl ester, monosodium salt	0.025	Field corn grain
22-3-05	I.2.2	iprovalicarb	[2-methyl-1[[[(1*S*)-(4-methylphenyl)ethyl] amino]carbonyl]propyl] carbamic acid methylethylester	2	Grapes
25-5-93	I.3	isofenphos	O-ethyl O-2-isopropoxy-carbonylphenyl isopropylphos-phoramidothioate including the metabolites 1-methylethyl-2-[[ethoxy[(1-methylethyl) amino] phosphinoxy]oxy] benzoate, 1-methylethyl-2-[[ethoxy(1-amino)phosphino-thioyl]oxy] benzoate and 1-methylethyl-2-[[ethoxy(1-amino) phosphinoxy]oxy] benzoate	0.01 0.02	Milk Eggs, rapeseed (canola)
22-3-05	I.3.1	isoxadifen-ethyl	ethyl 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylate	0.08	Field corn grain
25-10-01	I.4	isoxaflutole	(5-cyclopropyl-4-isoxazoly)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl] methanone, including the metabolite 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropylpropane, as parent equivalent	0.5 0.3 0.2 0.1 0.02 0.01	Liver of cattle Liver of poultry Meat of cattle, hogs, horses, poultry and sheep Meat by-products of cattle, hogs, horses, poultry and sheep Milk Eggs
			(5-cyclopropyl-4-isoxazoly)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl] methanone, including the metabolites 1-(2-methylsulfonyl-4-trifluorometylphenyl)-2-cyano-3-cyclopropylpropane and 2-metylslfonyl-4-trifluoromethyl benzoic acid, as parent equivalent	0.2	Corn

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
23-3-04	K.1	kresoxim-methyl	methyl (α*E*)-α-(methoxyimino)-2-[(2-methylphenoxy)methyl] benzeneacetate, including the metabolites (*E*)-2-[2-(2-methylphenoxymethyl) phenyl]-2-methoxyiminoacetic acid, 2-[2-(2-hydroxymethylphenoxy methyl)phenyl]-2-methoxyiminoacetic acid and 2-[2-(4-hydroxy-2-methyl-phenoxymethyl) phenyl]-2-methoxyiminoacetic acid	1.5	Raisins
			1	Grapes
25-10-01			0.5	Apples, crabapples, loquats, mayhaws, oriental pears, pears, quinces
			0.15	Apple juice, pear juice, pecans
			0.03	Meat and meat by-products of cattle, goats, hogs, horses and sheep
			0.004	Milk
	L.1	lindane	gamma isomer of benzene hexachloride (BHC)	3.0	Apples, apricots, asparagus, avocados, broccoli, Brussels sprouts, cabbage, cauliflower, celery, cherries, collards, cucumbers, eggplants, grapes, guavas, kale, kohlrabi, lettuce, mangoes, melons, mushrooms, mustard greens, okra, onions, peaches/nectarines, pears, peppers, pineapples, plums, pumpkins, quinces, spinach, squash, strawberries, Swiss chard, tomatoes
17-11-77				
23-5-02				
27-4-78				2.0 (calculated on the fat content)	Meat, meat by-products and fat of cattle, goats, hogs and sheep.
13-9-79				0.7 (calculated on the fat content)	Meat and meat by-products of poultry.
3-2-77				0.2 (calculated on the fat content)	Butter, cheese, milk and other dairy products.

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
23-5-02 25-8-76	M.1	malathion	diethyl mercapto-succinate *S*-(*O*,*O*-dimethyl phosphorodithioate)	8

TABLE II (continued)
AGRICULTURAL CHEMICALS

Item No.	I Common Chemical Name	II Chemical Name of Substance	III Maximum Residue Limit p.p.m.	IV Foods
19-11-03 13-4-00	M.3	metalaxyl	*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)-DL-alanine methyl ester, including metabolites containing the 2,6-dimethylaniline moiety	10 Onions (green), spinach 7 Asparagus 5 Citrus fruits, endives, lettuce 4 Avocados 3 Ginseng, onions (dry) 2 Blueberries, broccoli, cabbage, cauliflower, raisins 1 Apricots, cantaloupes, cherries, cucumbers, grapes, peaches/nectarines, peppers, plums, soybeans, squash,
23-5-02				sugar beets, tomatoes, watermelons 0.5 Almonds, carrots, potatoes, radishes, walnuts 0.4 Strawberries 0.2 Beans, peanuts, peas, raspberries, wheat 0.05 Barley

*(R) Minor correction

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
23-5-02 8-4-97	M.4	methamidophos	*O,S*-dimethyl phosphoramidothioate	1.0	Broccoli, Brussels sprouts, lettuce, peppers
23-11-95				0.5	Cabbage, cauliflower, celery, cucumbers, eggplants, tomatoes
				0.3	Beans
26-6-80	M.5	methidathion	*S*-(2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadoxol-3-ylmethyl)	2.0	Citrus fruits.
				0.5	Apples, pears.
23-5-02			*O,O*-dimethyl phosphorodithioate	0.2	Cherries, grapes, peaches/nectarines, plums.
8-4-97 21-10-99 26-6-80 9-8-78	M.6	methomyl	S-methyl-N-(methylcarbamoyloxy) thioacetimidate	6.0 5.0 4.0 2.0 1.0 0.5	Blueberries Cabbages Grapes Lettuce Citrus fruits, strawberries Apples, celery
23-3-04	M.6.1	(S)-methoprene	1-methylethyl (*E,E*)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate	0.05	Mushrooms
26-6-80 23-5-02 13-9-79	M.7	methoxychlor	1,1,1-trichloro-2,2-di-(4-methoxyphenyl) ethane	14.0	Apples, apricots, asparagus, beans, beets, blackberries, black-eyed peas, blueberries, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, cherries, collards, corn (in the husk) cranberries, cucumbers, currants, eggplants, gooseberries, grapes, kale, kohlrabi, lettuce, loganberries, melons, mushrooms, peaches/nectarines, peanuts, pears, peas, peppers, pineapples, plums, pumpkins, quinces, radishes, raspberries, spinach, squash, strawberries, summer squash, tomatoes, turnips (rutabagas).
				3.0 (calculated on the fat content)	Meat, meat by-products and fat of cattle, hogs and sheep.
				2.0	Barley, corn (as grain), oats, rice, rye, soybean, wheat.

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum residue Limit p.p.m.*	*Foods*
1-5-03	M.7.1	methoxyfenozide	3-methoxy-2-methylbenzoic acid, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide	1.5	Apples, crabapples, loquats, mayhaws, oriental pears, pear, quinces
				0.1	Fat, meat and meat by-products of cattle, goats, hogs, horses and sheep
			3-methoxy-2-methylbenzoic acid, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethyl-ethyl)hydrazide, including the metabolite β-D-Glucopyranuronic acid, 3-[[2-(1,1-dimethylethyl)-2-(3,5-dimethylbenzoyl)-hydrazino]carbonyl]-2-methylphenyl-	0.1	Kidney and liver of cattle, goats, hogs, horses and sheep
28-11-05	M.7.1.1	1-methyl-cyclopropene	1-methylcyclopropene	0.01	Apples
19-11-03	M.7.2	S-metolachlor	2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(*1S*)-2-methoxy-1-methylethyl)acetamide	0.3	Dry beans, lima beans, peas, snap beans
				0.2	Kidney of cattle, potatoes, soybeans
			and 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(*1R*)-2-methoxy-1-methylethyl)acetamide,	0.1	Apples, apricots, cherries, corn, peaches/nectarines, pears, plums, rutabagas, sugar beets, tomatoes
			including the metabolites	0.05	Liver of cattle and poultry
			2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone	0.02	Eggs, meat of cattle, goats, hogs, poultry and sheep, milk
21-10-99	M.8	metribuzin	4-amino-6-tert-butyl-3-methylthio-4,5-dihydro-1,2,4-triazin-5-one including the metabolites 6-tert-butyl-3-methylthio-4,5-dihydro-1,2,4-triazin-5-one, 4-amino-6-tert-butyl-2,3,4,5-tetrahydro-1,2,4-triazin-3,5-dione and 6-tert-butyl-2,3,4,5-tetrahydro-1,2,4-triazin-3,5-dione	0.5	Potatoes
18-12-75					

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
21-10-99	Item No.	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
1-31-02	M.8.1	metsulfuron-methyl	methyl 2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbony]amino]sulfonyl]benzoate, including the metabolite methyl 2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino] sulfonyl] 4-hydroxybenzoate	0.5 0.1 0.05	Kidney of cattle, goats and hogs Fat, meat and meat by-products of cattle, goats and hogs Milk
21-10-99 23-5-02	M.9	mevinphos	methyl 3-hydroxycrotonate dimethyl phosphate	0.25 0.2	Apples, asparagus, broccoli, Brussels sprouts, cabbage, cauliflower, celery, collards, kale, lettuce, mustard greens, onion (green), pears, peaches/nectarines, plums, raspberries, spinach, strawberries, tomatoes, turnip tops. Citrus fruits.
26-6-80	M.10	monocrotophos	dimethyl *cis*-1-methyl-2-methylcarbamoyl vinyl phosphate	1.0 0.5	Apples. Pears, tomatoes.
24-10-02 21-10-99	M.11	myclobutanil	α-butyl-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile, including the metabolites α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile and α-(butyl-3-one)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile	10 7 4 2 1 0.5 0.3	Raisins Dried peaches/nectarines Dried cherries Bananas Cherries, grapes, peaches/nectarines, peppers Apples, strawberries Balsam apples, balsam pears, bitter melons, cantaloupes, casaba melons, chayotes, Chinese cucumbers, Chinese waxgourds, citron melons, crenshaw melons, cucumbers, golden pershaw melons, gourds (edible), honey balls, honeydew melons, mango melons, Persian melons, pineapple melons, pumpkins, Santa Claus melons, snake melons, summer squash, watermelons, winter squash

*(R) Minor correction

	I	II	III	IV
21-10-99 Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
	M.11 myclobutanil (cont'd)	α-butyl-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile, including the metabolites α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile, α-(butyl-3-one)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile and α-(4-chlorophenyl)-α-(2-formylethyl)-1*H*-1,2,4-triazole-1-propane nitrile	0.3 0.05 0.02	Liver of cattle, goats, hogs, horses and sheep Fat, meat and meat by-products of cattle, goats, hogs, horses and sheep, milk Eggs, fat, meat and meat by-products of poultry
23-5-02	N.1 naled	1,2,-dibromo-2,2-dichloroethyl dimethyl phosphate	3	Chard, citrus fruits, spinach, turnip tops.
21-10-99			1	Broccoli, Brussels sprouts, cabbage, cauliflower, lettuce, strawberries.
			0.5	Beans, cucumbers, eggplants, melons, peas, peppers, pumpkins, rice, soybeans, squash, tomatoes.
1-5-03 13-4-00	N.1.1 nicosulfuron	2[[[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl]amino] sulfonyl]-*N,N*-dimethyl-3-pyridinecarboxamide	0.1 0.05	Corn Blueberries
25-8-76 8-3-79 4-3-75 23-5-02	N.2 nicotine	1-1-methyl-2-(3-pyridyl)pyrrolidine	2	Apples, apricots, artichokes, asparagus, beans, beets, beet tops, blackberries, black-eyed peas, boysenberries, broccoli, Brussels sprouts, cabbage, cantaloupes, cauliflower, celery, cherries, collards, corn, cucumbers, eggplants, grapefruit, green beans, onions (green), kale, kohlrabi, lemons, lettuce, lima beans, limes, mushrooms, muskmelons, mustard greens, okra, onions, oranges, parsley, parsnips, peaches/nectarines, pears, peas, peppers, pimentos, plums, prunes, pumpkins, quinces, radishes, rutabagas, snap beans, spinach, summer squash, Swiss chard, tangerines, tomatoes, turnips, watermelons, winter squash.

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
	Item No.	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
18-5-00	O.1	oxyfluorfen	2-chloro-α, α, α-trifluoro-*p*-tolyl 3-ethoxy-4-nitrophenyl ether	0.05	Strawberries
4-3-75	P.1	paraformaldehyde	paraformaldehyde	2 (Calculated as formaldehyde)	Maple syrup.
23-5-02	P.2	parathion	*O-O*-diethyl *O-p*-nitrophenyl phosphorothioate	0.7	Beans, red beets, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, celery, corn, cucumbers, eggplants, endives, kale, kohlrabi, lettuce, onions, parsnips, peas, peppers, pumpkins, radishes, spinach, squash, Swiss chard, tomatoes, turnips.
26-6-80 23-5-02				1.0	Apples, apricots, blackberries, blueberries, cherries, citrus fruits, cranberries, currants, gooseberries, grapes, hops, loganberries, melons, peaches/nectarines, pears, plums, quinces, raspberries, strawberries.
8-5-03	P.2.1	permethrin	(3-phenoxy-phenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-carboxylate	20	Leaf lettuce, spinach
12-4-84				10	Head lettuce
				5	Celery
				2	Grapes
19-11-96 23-5-02				1	Apples, peaches/nectarines, pears
				0.5	Beans, broccoli, Brussels sprouts, cabbage, cucumbers, peppers, plums, tomatoes, wasabi
				0.2 (calculated on the fat content)	Milk and other dairy products
				0.1 (calculated on the fat content)	Fat, meat and meat by-products of cattle and poultry
23-5-02	P.4	phosalone	*O,O*,diethyl S-(6-chloro-benzoxazolin-3-yl)-methyl phosphorodithioate	15.0	Artichokes.
13-5-75				12.0	Dried apricots
				6.0	Cherries.
27-4-78				5.0	Apples, grapes, plums.
23-5-02				4.0	Apricots, peaches/nectarines.
				2.0	Pears.
				1.5	Citrus fruits.

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
23-5-02 21-10-99	P.4.1	phosmet	*O,O*-dimethyl phthalimidomethyl phosphorodithioate	10.0	Apples, grapes, peaches/ nectarines, pears.
23-5-02				7.0	Cherries.
13-9-79				5.0	Blueberries, plums.
				1.0	Kiwi fruit (edible portion)
5-4-05	P.4.1.1	picloram	4-amino-3,5,6-trichloropicolinic acid	0.4	Kidney and meat by-products of cattle, goats, hogs, horses and sheep
				0.2	Kidney and meat by-products of poultry; wheat
				0.1	Barley
				0.05	Eggs; fat, liver and meat of cattle, goats, hogs, horses, poultry and sheep; milk
23-3-04	P.4.2	picolinafen	*N*-(4-fluorophenyl)-6-[3-(trifluoromethyl) phenoxy]-2-pyridinecarboxamide	0.05	Barley, wheat
	P.5	piperonyl butoxide	α-[2-(2-butoxyethoxy) ethoxy]-4,5-(methylene-dioxy)-2-propyltoluene	20	Raw cereals.
25-8-76 23-5-02				8	Almonds, apples, beans, blackberries, blueberries, boysenberries, cherries, cocoa beans, copra, crabapples, currants, dewberries, figs, gooseberries, grapes, guavas, huckleberries, loganberries, mangoes, muskmelons, oranges, peaches/ nectarines, peanuts, pears, peas, pineapple, plums, raspberries, tomatoes, walnuts.
				1	Dried codfish.
24-9-02 21-10-99 5-5-83	P.5.1	pirimicarb	2-(dimethylamino)-5,6-dimethyl pyrimidin-4-yl dimethylcarbamate including the metabolites 2-(formyl methylamino)-5-6-dimethyl pyrimidin-4-yl dimethylcarbamate and 2-(methylamino)-5-6-dimethyl pyrimidin-4-yl dimethylcarbamate.	0.5	Apples
				0.2	Spinach
				0.1	Celery

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
30-1-01	P.5.1.1	primisulfuron-methyl	2-[4,6-bis(difluoromethoxy) pyrimidin-2-ylcarbamoylsulfamoyl] benzoic acid, methyl ester	0.1 0.02	Eggs, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep Corn, milk
20-11-97	P.5.2	procymidone	N-(3,5-dichlorophenyl)-1,2-dimethylcyclopropane-1,2-dicarboximide	25.0 5.0 1.0	Raisins Grapes Wine
21-10-99 23-5-02 7-10-82	P.6	propargite	2-(4-*tert*-butylphenoxy) cyclohexylprop-2-ynyl sulphite	30.0 7.0 5.0 3.0	Hops (dried) Apricots, grapes, peaches/nectarines, strawberries. Beans, citrus fruits, cranberries, plums Apples, pears.
25-10-01	P.6.1	propamocarb hydrochloride	propyl [3-(dimethylamino)propyl] carbamate hydrochloride	2 0.5	Cucumbers Potatoes
7-11-02 13-9-00	P.7	propiconazole	1-[[2-(2,4-diclorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole including all metabolites containing the 2,4-dichlorophenyl-1-methyl substituted moiety	2 1 0.15 0.1 0.05 0.02	Liver and kidney of cattle Apricots, cherries, peaches/nectarines, plums Dried blueberries Asparagus Barley, oats, wheat Blueberries
23-5-02 25-7-97	P.7.1	propyzamide	3,5-dichloro-N-(1,1-dimethylpropynyl)-benzamide including its metabolites containing the 3,5-dichlorobenzoate moiety	1.0	Lettuce
23-6-99	P.7.2	prosulfuron	1-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-3-[2-(3,3,3-trifluoro-propyl)phenylsulfonyl] urea	0.05 0.01	Eggs, meat and meat by-products Corn, milk
25-8-76 8-3-79 23-5-02	P.8	pyrethrins	4-hydroxy-3-methyl-2-(2,4-pentadienyl)-2-cyclopenten-1-one 2,2-dimethyl-3-(2-methyl-propenyl) cyclopropane-carboxylate and 4-hydroxy-3-methyl-2-(2,4-pentadienyl)2-cyclopenten-1-one 1-methyl 3-carboxy-α,2,2-trimethylcyclo-propaneacrylate ester.	3 1	Raw cereals. Almonds, apples, beans, blackberries, blueberries, boysenberries, cherries, cocoa beans, copra, crabapples, currants, dewberries, figs, gooseberries, grapes, guavas, huckleberries, loganberries, mangoes, muskmelons, oranges, peaches/nectarines, peanuts, pears, peas, pineapple, plums, raspberries, tomatoes, walnuts.

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
24-10-02	P.8.01	pyridaben	4-chloro-2-(1,1-dimethylethyl)-5-[[[4-(1,1-dimethylethyl) phenyl]methyl]thio]-3(2*H*)-pyridazinone	2	Strawberries
				1.5	Peaches/nectarines
20-9-01				1	Peppers
				0.75	Pears
				0.5	Apples
				0.3	Grapes
				0.15	Tomatoes
				0.1	Cucumbers
				0.05	Almonds, meat of cattle, goats, horses and sheep
				0.01	Milk
1-02-00	P.8.1	pyrimethanil	4,6-dimethyl-*N*-phenyl-2-pyrimidinamine	8	Raisins
26-10-04				5	Grapes
				0.05	Bananas
23-5-02	Q.01	quinclorac	3,7-dichloroquinolin-8-carboxylic acid	5	Rice
1-02-00				2	Barley
				0.5	Wheat
				0.05	Eggs, meat, meat by-products and fat of cattle, goats, hogs, horses, poultry and sheep; milk
23-5-02	Q.1	quizalofop-ethyl	ethyl (*RS*) 2-[4-(6-chloroquinoxalin-2-yloxy) phenoxy] propionate, including the acid metabolites of (*RS*)2-[4-(6-chloroquinoxalin-2-yloxy) phenoxy] propanoic acid, all expressed as quizalofop-ethyl	0.2	Sugar beets
				0.05	Fat and meat by-products of cattle, goats, hogs, horses, poultry and sheep, flax, lentils, milk fat, peas, rapeseed (canola), soybeans
28-1-93					
21-10-99					
13-4-00					
				0.02	Eggs, meat of cattle, goats, hogs, horses, poultry and sheep
				0.01	Milk
23-3-04	R.1	rimsulfuron	*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide	0.05	Blueberries, tomatoes
24-10-02					
7-11-2	S.1	sethoxydim	(±)-2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio) propyl]-3-hydroxy-2-cyclohexen-1-one and metabolites containing the cyclohexen-2-one moiety expressed as sethoxydim	30	Lentils
				15	Tomato paste
28-8-97				10	Dry beans, peas, strawberries
				7	Sunflowers
				5	Beans, raspberries, soybeans
				4	Blueberries, potatoes, tomatoes
				2	Artichokes, cabbage, cantaloupes, cranberries, eggplants, eggs, mustard, mustard greens, spinach
				1	Celery, cucumbers, lettuce, pumpkins, squash
				0.5	Asparagus, broccoli, corn, peppers, liver of poultry
				0.2	Flax, onions, meat of poultry, turnips
				0.1	Carrots

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
23-5-02 21-10-99 25-8-76	S.2	sodium orthophenyl phenate	o-phenyl phenol, sodium salt	25* 20* 15* 10* 5* *(calculated as ortho-phenyl-phenol)	Apples, pears. Carrots, peaches/nectarines, plums. Sweet potatoes. Cantaloupes (edible portion), citrus fruits, cucumbers, peppers (bell), pineapple, tomatoes. Cherries
4-12-86	S.3	sodium TCA	sodium trichloroacetate	0.5 (calculated as trichloro-acetic acid)	Barley, oats.
23-3-04	S.3.1	spinosad	(2*R*,3a*S*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)-tetrahydro-6-methyl-2*H*-pyran-2yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione (spinosyn A) and (2*S*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)-tetrahydro-6-methyl-2*H*-pyran-2yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione (spinosyn D)	0.1 0.02	Apples Potatoes

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	*Item No.*	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
7-11-02	S.4	sulfosulfuron	*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl]-2-(ethylsulfonyl) imidazo[1,2-α]pyridine-3-sulfonamide and all metabolites containing the imidazopyridine moiety, expressed as sulfosulfuron	0.02	Wheat
20-9-01	T.001	tebuconazole	(±)-α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol	5 3 1 0.1 0.05 0.03 0.01	Grapes Cherries Peaches/nectarines Peanuts Wheat Bananas Barley, oats
			(±)-α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, including the metabolite 5-(4-chlorophenyl)-2,2-dimethyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)-1,3-pentanediol	0.2 0.1	Meat and meat by-products of cattle, goats, hogs, horses and sheep Eggs, meat and meat by-products of poultry, milk
7-11-02 25-10-01 28-7-99 28-8-97	T.01	tebufenozide	3,5-dimethylbenzoic acid 1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide	6 5 2.5 2 1 0.5 0.2	Lettuce Dried cranberries Raisins Tomatoes Apples, cranberries, pears Grapes, kiwi fruit Peppers

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
23-5-02 25-5-93	T.1.0	tefluthrin	0.001	Milk
23-5-02 21-10-99 25-5-93	T.1.1	tetrachlorvinphos	10 1.5 (calculated on the fat content) 0.75 (calculated on the fat content)	Apples, grapes. Meat, meat by-products and fat of cattle and hogs. Meat, meat by-products and fat of poultry.
21-10-99 23-5-02	T.1.2	tetradifon	1 2 5 10 100	Cucumbers, melons, pumpkins, summer squash, tomatoes, watermelons, winter squash. Citrus fruits. Apples, crabapples, apricots, cherries, grapes, peaches/ nectarines, pears, plums, prunes, quinces, strawberries. Figs. Peppermint, spearmint.
3-2-77	T.2	thiabendazole	10 4.0 0.4	Apples, citrus fruits, pears Potatoes Bananas (edible pulp)
8-5-03 25-10-01	T.2.01	thiamethoxam	0.02 0.01	All food crops, eggs, meat and meat by-products of cattle, hogs, poultry and sheep Milk
1-5-03 18-5-00	T.2.1	thifensulfuron-methyl	methyl-3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] amino]sulfonyl]-2-thiophenecarboxylate	0.07 0.02 Tomatoes Flax, rapeseed (canola)
4-3-75 23-5-02	T.3	thiram	bis (dimethylthiocarbamoyl) disulphide	1 7 Bananas (edible pulp) Apples, celery, peaches/nectarines, strawberries, tomatoes

TABLE II (continued)
AGRICULTURAL CHEMICALS

		I	II	III	IV
21-10-99	Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
4-5-93	T.5	tralkoxydim	2-[1-(ethoxy-imino) propyl]-3-hydroxy-5-mesitylcyclohex-2-enone	0.02	Barley, wheat
25-5-93	T.5.1	triasulfuron	1-[2-(2-chloroethoxy)-phenylsulphonyl]-3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) urea	0.02	Wheat
21-10-99 4-5-93	T.6	triazolyl alanine plant metabolite from triazole fungicides	triazol-1-yl alanine (TA)	2	All food crops
31-1-02 4-5-93	T.7	tribenuron-methyl	methyl 2-[[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)methylamino] carbonyl]amino]sulfonyl] benzoate	0.05 0.02 0.01	Barley, oats, wheat Flax, rapeseed (canola) Milk
23-1-96	T.7.1	triclopyr	3,5,6-trichloro-2-pyridyloxyacetic acid including the metabolite 3,5,6-trichloro-2-pyridinol	0.5	Liver and kidney of cattle, goats, hogs, horses and sheep
5-4-05	T.7.2	triflumizole	1-[1-[[4-chloro-2-(trifluoromethyl) phenyl]imino]-2-propoxyethyl]-1*H*-imidazole, including metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, expressed as triflumizole	2.5 1.5 0.5	Grapes Sour cherries, sweet cherries Apples, pears
4-5-93	T.8	trifluralin	α,α,α-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine	0.5	Carrots
18-5-00	T.8.1	triflusulfuron-methyl	methyl 2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoylsulfamoyl]-*m*-toluate	0.05	Molasses, sugar, sugar beets

TABLE II (continued)
AGRICULTURAL CHEMICALS

	I	II	III	IV
Item No.	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
21-10-99				
16-11-04	T.9	trimethylsulfonium cation	trimethylsulfonium cation	15	Barley, oat milling fractions, excluding flour
24-10-02				13	Soybeans
5-2-98				10	Oats, rapeseed (canola)
				3	Flax, peas, wheat
				1.5	Lentils
				1	Beans; kidney of cattle, goats, hogs, horses and sheep
				0.5	Liver of cattle, goats, hogs and sheep; meat and meat by-products of cattle, goats, hogs, horses and sheep; milk
				0.1	Kidney and liver of poultry
				0.05	Meat of poultry
				0.02	Eggs
22-11-01	T.10	triticonazole	5-[(4-chlorophenyl) methylene]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl) cyclopentanol	0.05	Eggs, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep
				0.01	Barley, milk, oats, wheat

	I	II	III	IV
	Item No.	*Common Chemical Name*	*Chemical Name of Substance*	*Maximum Residue Limit p.p.m.*	*Foods*
23-6-95	V.1	vinclozolin	3-(3,5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione including metabolites containing the 3,5-dichloroaniline moiety expressed as vinclozolin	10.0 5.0 3.0 2.0 1.0	Kiwi fruit, strawberries Apricots, grapes, lettuce Cherries, tomatoes Peaches/nectarines, peppers Beans, cucumbers, plums
4-3-75 21-10-99 23-5-02	Z.2	ziram	zinc dimethyldithiocarbamate	7 (calculated as zineb)	Apples, apricots, beans, beets, blackberries, black-eyed peas, blueberries (Huckleberries), broccoli, Brussels sprouts, cabbage, carrots, cauliflower, celery, cherries, collards, cranberries, cucumbers, eggplants, gooseberries, grapes, kale, kohlrabi, lettuce, loganberries, melons, onions, peaches/nectarines, peanuts, pears, peas, peppers, pumpkins, quinces, radishes, raspberries, rutabagas, spinach, squash, strawberries, summer squash, tomatoes, turnips.
24-10-02	Z.3	zoxamide	3,5-dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide 3,5-dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide, including the metabolites 3,5-dichloro-1,4-benzene-dicarboxylic acid and 3,5-dichloro-4-hydroxymethyl benzoic acid	15 3 0.3 0.06	Raisins Grapes Potato processed fractions (chips, flakes and granules) Potatoes

TABLE III
VETERINARY DRUGS

	Column I	Column II	Column III	Column IV
5-10-92	*Item No.*	*Common Name (or Brand Name) of Drug*	*Name of substance for Drug Analysis Purposes*	*Maximum Residue Limit p.p.m.*	*Foods*
31-1-02	A.01	albendazole	albendazole-2-aminosulfone	0.2	Liver of cattle
	A.1	ampicillin	ampicillin	0.01	Edible tissue of swine and cattle; milk
	A.2	amprolium	amprolium	0.5	Muscle of chickens and turkeys
				1.0	Liver and kidney of chickens and turkeys
				7.0	Eggs
	A.3	apramycin	apramycin	0.1	Kidney of swine
	A.4	arsanilic acid	arsenic	0.5	Muscle of swine, chickens and turkeys; eggs
				2.0	Liver of swine, chickens and turkeys
	B.1	buquinolate	buquinolate	0.1	Muscle of chickens
				0.4	Liver, kidney, skin and fat of chickens
28-11-05	C.01	ceftiofur	desfuroyl-ceftiofur (DFC)	0.1	Milk
				1.0	Muscle of cattle, sheep and swine
				2.0	Liver and fat of cattle, sheep and swine
				5.0	Kidney of swine
				6.0	Kidney of cattle and sheep
11-4-91	C.1	cephapirin	cephapirin	0.02	Milk
				0.1	Edible tissue of cattle
	C.2	chlortetra-cycline	chlortetracycline	0.1	Kidney, liver and muscle of cattle; muscle of sheep
				0.2	Fat of swine
				0.5	Liver of sheep
				1.0	Muscle, liver, skin and fat of chickens and turkeys; muscle of swine; muscle and fat of calves; kidney of sheep
				2.0	Liver of swine
				4.0	Kidney of swine, chickens and turkeys; liver and kidney of calves.
	C.3	clopidol	clopidol	5.0	Muscles of chickens and turkeys
				15.0	Liver and kidney of chickens and turkeys
	D.1	decoquinate	decoquinate	1.0	Muscle of cattle, goats and chickens
				2.0	Kidney, liver and fat of cattle and goats; kidney, liver, skin and fat of chickens
	D.2	dihydrostrep-tomycin	dihydrostreptomycin	0.125	Milk

TABLE III
VETERINARY DRUGS -- (continued)

5-10-92	Item No.	Column I Common Name (or Brand Name) of Drug	Column II Name of Substance for Drug Analysis Purposes	Column III Maximum Residue Limit p.p.m.	Column IV Foods
	D.3	dinitolmide (zoalene)	dinitolmide, including the metabolite 3-amino-5-nitro-o-toluamide	2.0 3.0 6.0	Fat of chickens Muscle of chickens and turkeys; liver and fat of turkeys Liver and kidney of chickens
	E.1	erythromycin	erythromycin	0.05 0.1 0.125	Milk Edible tissue of swine Edible tissue of chickens and turkeys
31-2-02	F.1	fenbendazole	fenbendazole	0.45 4.5	Liver of cattle Liver of swine
31-1-02	F.2	florfenicol	florfenicol amine	0.82	Muscle of salmonids Liver of cattle
	G.1	gentamicin	gentamicin	0.1 0.4	Edible tissue of turkeys Kidney of swine
31-1-02	H.01	halofuginone	halofuginone	0.1	Liver of chicken
	H.1	hydrocortisone	hydrocortisone	0.01	Milk
31-1-02	I.1	ivermectin	22,23-dihydro-avermectin B_{1a}	0.015 0.03 0.07	Liver of swine Liver of sheep Liver of cattle
31-1-02	L.01	lasalocid	lasalocid	0.35 0.65	Fat and skin of chicken Liver of cattle
	L.1.	levamisole hydrochloride	levamisole	0.1 (calculated as levamisol hydro-chloride	Edible tissue of cattle, sheep and swine
31-1-02	M.01	maduramicin	maduramicin	0.4	Fat and skin of chicken
28-11-05	M.1	monensin	monensin	0.05	Edible tissue of cattle, chickens and turkeys
31-1-02	M.2	morantel tartrate	N-methyl-1,3-propane diamine	0.1 0.5	Milk Liver of cattle
31-1-02	M.3	moxidectin	moxidectin	0.55	Fat of cattle
31-1-02	N.01	narasin	narasin	0.5	Fat of chicken
	N.1	neomycin	neomycin	0.25	Edible tissue of calves
	N.2	nicarbazin	**N**,**N**^{1}-bis(4-nitrophenyl)urea	4	Muscle, liver, kidney and skin of chickens
	N.3	nitarsone	arsenic	0.5 2.0	Muscle of turkeys Liver of turkeys
	N.4	novobiocin	novobiocin	1	Edible tissue of cattle, chickens and turkeys

TABLE III
VETERINARY DRUGS -- (continued)

	Column I	Column II	Column III	Column IV
5-10-92	*Item No.*	*Common Name (or Brand Name) of Drug*	*Name of Substance for Drug Analysis Purposes*	*Maximum Residue Limit p.p.m.*	*Foods*
31-1-02	P.1	pencillin G	penicillin G	0.01 I.U./ml 0.01 0.05	Milk Edible tissue of turkeys Edible tissue of cattle and swine
28-11-05	P.1.1	pirlimycin	pirlimycin	0.3 0.4 0.5	Muscle of cattle Milk Liver of cattle
	P.2	polymyxin B	polymyxin B	4.0 u/ml	Milk
	P.3	pyrantel tartrate	N-methyl-1,3-propane-diamine	1.0 (calculated as pyrantel tartrate) 10.0 (calculated as pyrantel tartrate)	Muscle of swine Liver and kidney of swine
	R.1	robenidine hydro-chloride	robenidine	0.1 (calculated as robenidine hydro-chloride) 0.2 (calculated as robenidine hydro-chloride)	Muscle, liver and kidney of chickens Skin and fat of chickens
	R.2	roxarsone	arsenic	0.5 2.0	Muscle of swine, chickens and turkeys; eggs Liver of swine, chickens and turkeys
31-1-02	S.01	salinomycin	salinomycin	0.35	Fat and skin of chicken; Liver of cattle and swine
	S.1	spectinomycin	spectinomycin	0.1	Edible tissue of chickens
	S.2	streptomycin	streptomycin	0.125	Milk
	S.3	sulfachlor-pyridazine	sulfachlorpyridazine	0.1	Edible tissue of cattle and swine
31-1-02	S.3.1	sulfadiazine	sulfadiazine	0.1	Muscle of salmonids
11-4-91	S.4	sulfadimethoxine	sulfadimethoxine	0.01 0.1	Milk Edible tissue of cattle
	S.5	sulfaethoxy-pyridazine	sulfaethoxypyridazine	0.1	Edible tissue of cattle

TABLE III
VETERINARY DRUGS -- (concluded)

	Item No.	Column I Common Name (or Brand Name) of Drug	Column II Name of Substance for Drug Analysis Purposes	Column III Maximum Residue Limit p.p.m.	Column IV Foods
31-1-02	S.6	sulfamethazine	sulfamethazine	0.01 0.1	Milk Edible tissue of calves, cattle, chickens, swine and turkeys
	S.7	sulfathiazole	sulfathiazole	0.1	Edible tissue of swine
28-11-05	T.01	teflubenzuron	teflubenzuron	0.3 3.2	Muscle of salmonids Skin of salmonids
	T.1	tetracycline	tetracycline	0.25	Edible tissue of calves, swine, sheep, chickens and turkeys
	T.2	thiabendazole	thiabendazole and total 5-hydroxy-thiabendazole metabolites (free form, glucuronide and sulfate conjugates)	0.05 0.1	Milk Edible tissue of cattle, goats and sheep
	T.3	tiamulin	8-alpha-hydroxy-mutilin	0.4	Liver of swine
31-1-02	T.3.1	tilmicosin	tilmicosin	1.6	Liver of cattle
31-1-02	T.3.2	trimethoprim	trimethoprim	0.1	Muscle of salmonids
	T.4	tylosin	tylosin	0.2	Muscle, liver, kidney and fat of cattle, swine, chickens and turkeys

Food Additives

13-5-75 **B.16.001.** A quantitative statement of the amount of each additive present or directions for use that, if followed, will produce a food that will not contain such additives in excess of the maximum levels of use prescribed by these Regulations shall be shown, grouped together with the list of ingredients, of any substance or mixture of substances for use as a food additive.

B.16.002. A request that a food additive be added to or a change made in the Tables following section B.16.100 shall be accompanied by a submission to the Minister in a form, manner and content satisfactory to him and shall include

(a) a description of the food additive, including its chemical name and the name under which it is proposed to be sold, its method of manufacture, its chemical and physical properties, its composition and its specifications and, where that information is not available, a detailed explanation;
(b) a statement of the amount of the food additive proposed for use, and the purpose for which it is proposed, together with all directions, recommendations and suggestions for use;
(c) where necessary, in the opinion of the Director, an acceptable method of analysis suitable for regulatory purposes that will determine the amount of the food additive and of any substance resulting from the use of the food additive in the finished food;
3-9-64 (d) data establishing that the food additive will have the intended physical or other technical effect;
(e) detailed reports of tests made to establish the safety of the food additive under the conditions of use recommended;
(f) data to indicate the residues that may remain in or upon the finished food when the food additive is used in accordance with good manufacturing practice;
(g) a proposed maximum limit for residues of the food additive in or upon the finished food;
(h) specimens of the labelling proposed for the food additive; and
(i) a sample of the food additive in the form in which it is proposed to be used in foods, a sample of the active ingredient, and, on request a sample of food containing the food additive.

B.16.003. The Minister shall, within ninety days after the filing of a submission in accordance with section B.16.002, notify the person filing the submission whether or not it is his intention to recommend to the Governor-in-Council that the said food additive be so listed and the detail of any listing to be recommended.

19-3-97 **B.16.004.** Repealed by P.C. 1997-378 of March 19, 1997.

3-9-64 **B.16.006.** Paragraph (c) of section B.01.042 and paragraph (a) of section B.01.043 do not apply to spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives.

6-11-87 **B.16.007.** No person shall sell a food containing a food additive other than a food additive provided for in sections B.01.042, B.01.043 and B.25.062.

11-8-88 **B.16.008.** Revoked by P.C. 1988-1604 of August 11, 1988.

3-9-64 **B.16.100.** No person shall sell any substance as a food additive unless the food additive is listed in one or more of the following Tables:

*(R) Minor correction

TABLE N°	TITLE	PAGE(S)
I	FOOD ADDITIVES THAT MAY BE USED AS ANTICAKING AGENTS	205 to 208
II	FOOD ADDITIVES THAT MAY BE USED AS BLEACHING, MATURING AND DOUGH CONDITIONING AGENTS	209 to 210
III	FOOD ADDITIVES THAT MAY BE USED AS COLOURING AGENTS	211 to 215
IV	FOOD ADDITIVES THAT MAY BE USED AS EMULSIFYING, GELLING, STABILIZING, AND THICKENING AGENTS	217 to 247
V	FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES	249 to 260a
VI	FOOD ADDITIVES THAT MAY BE USED AS FIRMING AGENTS	261 to 262
VII	FOOD ADDITIVES THAT MAY BE USED AS GLAZING AND POLISHING AGENTS	263
VIII	MISCELLANEOUS FOOD ADDITIVES	265 to 281
IX	FOOD ADDITIVES THAT MAY BE USED AS SWEETENERS	283 to 286
X	FOOD ADDITIVES THAT MAY BE USED AS pH ADJUSTING AGENTS, ACID-REACTING MATERIALS AND WATER CORRECTING AGENTS	287 to 301
XI I	FOOD ADDITIVES THAT MAY BE USED AS CLASS I PRESERVATIVES	303 to 310
II	FOOD ADDITIVES THAT MAY BE USED AS CLASS II PRESERVATIVES	311 to 315
III	FOOD ADDITIVES THAT MAY BE USED AS CLASS III PRESERVATIVES	316 to 317
IV	FOOD ADDITIVES THAT MAY BE USED AS CLASS IV PRESERVATIVES	319 to 325
XII	FOOD ADDITIVES THAT MAY BE USED AS SEQUESTERING AGENTS	327 to 330
XIII	FOOD ADDITIVES THAT MAY BE USED AS STARCH MODIFYING AGENTS	331 to 332
XIV	FOOD ADDITIVES THAT MAY BE USED AS YEAST FOODS	333 to 334
XV	FOOD ADDITIVES THAT MAY BE USED AS CARRIER OR EXTRACTION SOLVENTS	335 to 339

TABLE I

FOOD ADDITIVES THAT MAY BE USED AS ANTICAKING AGENTS

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
C.1	Calcium Aluminum Silicate	(1) Salt	(1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a).
13-9-79		(2) Garlic Salt; Onion Salt	(2) 2.0% in accordance with the requirement of paragraphs B.07.020(b) and B.07.027(b) respectively.
		(3) Unstandardized dry mixes	(3) Good Manufacturing Practice
C.2	Calcium Phosphate, tribasic	(1) Salt	(1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a).
13-9-79		(2) Garlic Salt; Onion Salt	(2) 2.0% in accordance with the requirement of paragraph B.07.020(b) and B.07.027(b) respectively.
12-12-71		(3) Dry cure	(3) Good Manufacturing Practice
		(4) Unstandardized dry mixes	(4) Good Manufacturing Practice
		(5) Oil soluble annatto	(5) Good Manufacturing Practice
		(6) Icing sugar	(6) If used either singly or in combination with Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Magnesium Stearate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5%.
C.3	Calcium Silicate	(1) Salt	(1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a)
13-9-79		(2) Garlic Salt; Onion Salt	(2) 2.0% in accordance with the requirement of paragraphs B.07.020(b) and B.07.027(b) respectively
		(3) Baking Powder	(3) 5.0%
		(4) Dry cure	(4) Good Manufacturing Practice
		(5) Unstandardized dry mixes	(5) Good Manufacturing Practice
21-12-71		(6) Icing sugar	(6) If used either singly or in combination with Calcium Phosphate, tribasic, Magnesium Carbonate, Magnesium Silicate, Magnesium Stearate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5%.
7-10-82			
31-12-90		(7) Meat Binder or (naming the meat product) Binder	(7) 1.0%
8-4-97		(8) Grated or shredded (named variety) cheese; Grated or shredded cheddar cheese; Unstandardized grated or shredded cheese preparations	(8) If used singly or in combination with microcrystalline cellulose or cellulose, the total amount not to exceed 2.0%.
28-4-94		(9) Dried whole egg; Dried egg white (dried albumen); Dried egg yolk; Dried whole egg mix; Dried egg yolk mix	(9) 2.0%

*(R) Minor correction

TABLE I -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
13-9-79	C.4	Calcium Stearate	(1) Salt (2) Garlic Salt; Onion Salt (3) Unstandardized dry mixes	(1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a). (2) 2.0% in accordance with the requirement of paragraphs B.07.020(b) and B.07.027(b) respectively. (3) Good Manufacturing Practice
8-4-97 23-9-93	C.5	Cellulose	Grated or shredded (named variety) cheese; Grated or shredded cheddar cheese; Unstandardized grated or shredded cheese preparations	If used singly or in combination with calcium silicate or microcrystalline cellulose, the total amount not to exceed 2.0%
23-6-71 13-9-79 21-12-71	M.1	Magnesium Carbonate	(1) Salt (except when used in preparations of meat and meat by-products of Divisi on 14) (2) Garlic salt; Onion Salt (except when used in prep arations of meat and meat by-products of Division 14) (3) Unstandardized Dry Mixes (Except when used in preparations of meat and meat by-products of Division 14) (4) Icing sugar	(1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a) (2) 2.0% in accordance with the requirement of paragraphs B.07.020(b) and B.07.027(b) respectively (3) Good Manufacturing Practice (4) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Silicate, Magnesium Stearate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5%.
	M.2	Magnesium Oxide	Unstandardized dry mixes (Except when used in preparations of meat and meat by-products of Division 14)	Good Manufacturing Practice
13-9-79 21-12-71	M.3	Magnesium Silicate	(1) Salt (2) Garlic salt; Onion salt (3) Unstandardized dry mixes (4) Icing sugar	(1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a). (2) 2.0% in accordance with the requirement of paragraphs B.07.020(b) and B.07.027(b) respectively. (3) Good Manufacturing Practice (4) If used either singly or in combination with Calcium Silicate, Magnesium Carbonate, Magnesium Stearate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5%.

*(R) Minor correction

TABLE I -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
13-9-79 21-12-71	M.4	Magnesium Stearate	(1) Salt (2) Garlic Salt; Onion Salt (3) Unstandardized dry mixes (4) Icing Sugar	(1) 1.0% except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a) (2) 2.0% in accordance with the requirement of paragraphs B.07.020(b) and B.07.027(b) respectively (3) Good Manufacturing Practice (4) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5%.
8-4-97 17-10-83 23-9-93	M.5	Microcrystalline Cellulose	Grated or shredded (named variety) cheese; Grated or shredded cheddar cheese; Unstandardized grated or shredded cheese preparations	If used singly or in combination with calcium silicate or cellulose, the total amount not to exceed 2.0%
13-9-79 28-9-67	P.1	Propylene Glycol	Salt	0.035%
   11-10-84	S.1	Silicon Dioxide	(1) Garlic Salt; Onion salt (2) Celery Salt; Celery Pepper (3) Unstandardized dry mixes (4) Icing sugar (5) Foods sold in tablet form (6) Cayenne Pepper; Chili pepper; Chili powder; Paprika; Red Pepper (7) Salt	(1) 1.0% in accordance with the requirement of paragraphs B.07.020(b) and B.07.027(b) respectively. (2) 0.5% (3) Good Manufacturing Practice (4) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Magnesium Stearate or Sodium Aluminum Silicate the total must not exceed 1.5%. (5) Good Manufacturing Practice (6) 2.0%. (7) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a).
4-12-86 15-6-67	S.2	Sodium Aluminum Silicate	(1) Salt (2) Icing sugar (3) Dried whole egg; Dried egg white (dried albumen); Dried egg yolk; Dried whole egg mix; Dried egg yolk mix (4) Garlic salt; Onion salt (5) Unstandardized dry mixes	(1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a). (2) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Magnesium Stearate or Silicon Dioxide the total must not exceed 1.5%. (3) 2.0% (4) 2.0% in accordance with the requirement of paragraphs B.07.020(b) and B.07.027(b) respectively. (5) Good Manufacturing Practice.

*(R) Minor correction

TABLE I -- (concluded)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
S.3	Sodium Ferrocyanide, decahydrate	Salt	13 ppm calculated as anhydrous sodium ferrocyanide

13-9-79

TABLE II

FOOD ADDITIVES THAT MAY BE USED AS BLEACHING, MATURING AND DOUGH CONDITIONING AGENTS.

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
5-4-05	A.1	Acetone Peroxide	(1) Bread; Flour; Whole wheat flour (2) Unstandardized bakery foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
	A.2	Ammonium Persulphate	(1) Flour; Whole wheat flour (2) Bread (3) Unstandardized bakery foods	(1) 250 p.p.m. (2) 100 p.p.m. of flour (3) Good Manufacturing Practice
15-6-68	A.2A	Ascorbic Acid	(1) Bread; Flour; Whole wheat flour (2) Unstandardized bakery foods	(1) 200 p.p.m. of flour (2) 200 p.p.m. of flour
	A.4.	Azodicarbo n-amide	Bread; Flour; whole wheat flour	45 p.p.m. of flour
	B.1	Benzoyl Peroxide	Flour; Whole wheat flour	150 p.p.m.
10-3-70	C.1	Calcium Iodate	(1) Bread (2) Unstandardized bakery foods	(1) 45 p.p.m. of flour (2) 45 p.p.m. of flour
	C.2	Calcium Peroxide	(1) Bread (2) Unstandardized bakery foods	(1) 100 p.p.m. of flour (2) Good Manufacturing Practice
23-1-74	C.3	Calcium stearoyl-2-Lactylate	(1) Bread (2) Unstandardized bakery foods (3) Cake mixes	(1) 3750 p.p.m. of flour (2) 3750 p.p.m. of flour (3) 0.5% of dry weight of mix
	C.4	Chlorine	Flour, Whole wheat flour	Good Manufacturing Practice
	C.5	Chlorine Dioxide	Flour, Whole wheat flour	Good Manufacturing Practice
15-5-68 6-11-87 5-10-92	C.6	L-Cysteine Hydro-chloride	(1) Bread; Flour; Whole wheat flour (2) Unstandardized bakery foods	(1) 90 p.p.m. (2) Good Manufacturing Practice

*(R) Minor correction

TABLE II -- (concluded)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
1-3-94	P.1	Revoked by P.C. 1994-362 of March 1, 1994.	
10-3-70	P.2 Potassium Iodate	(1) Bread (2) Unstandardized bakery foods	(1) 45 p.p.m. of flour (2) 45 p.p.m. of flour
	P.3 Potassium Persulphate	(1) Bread (2) Unstandardized bakery foods	(1) 100 p.p.m. of flour (2) Good Manufacturing Practice
23-1-74	S.1 Sodium stearoyl-2-Lactylate	(1) Bread (2) Unstandardized bakery foods (3) Pancake and pancake mixes (4) Waffles and waffle mixes (5) Cake mixes	(1) 3750 p.p.m. of flour (2) 3750 p.p.m. of flour (3) 0.3% of dry ingredient weight (4) 0.3% of dry ingredient weight (5) 0.5% of dry weight of mix
	S.2 Sodium stearyl fumarate	(1) Bread (2) Unstandardized bakery foods	(1) 5000 p.p.m. of flour (2) 5000 p.p.m. of flour
	S.3 Sodium Sulphite	Biscuit dough	500 p.p.m. calculated as Sulphur Dioxide

TABLE III
FOOD ADDITIVES THAT MAY BE USED AS COLOURING AGENTS

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
1.	Aluminum Metal Alkanet Annatto Anthocyanins Beet Red Canthax-anthin Carbon Black Carotene Charcoal Chlorophyll Cochineal Iron Oxide Orchil Paprika Riboflavin Saffron Saunderswood Silver Metal Titanium Dioxide Turmeric Xanthophyll	(1) Apple (or rhubarb) and (naming the fruit) jam; Bread; Butter; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin; Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Liqueurs and alcoholic cordials; (naming the flavour) milk; Pickles and relishes; Pineapple marmalade with pectin; Sherbet; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) skim milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Tomato catsup; Marinated or similar cold-processed packaged fish and meat (Division 21)	(1) Good Manufacturing Practice
6-4-89 13-5-75 28-4-74		(2) Liquid, dried or frozen whole egg; Liquid, dried or frozen egg yolk.	(2) Good Manufacturing Practice in accordance with paragraphs B.22.034(b) and B.22.035(b)
		(3) Unstandardized foods	(3) Good Manufacturing Practice
17-11-77		(4) Vegetable fats and oils	(4) Good Manufacturing Practice in accordance with section B.09.001
23-9-93		(5) Margarine	(5) Good Manufacturing Practice
		(6) (named variety) Cheese; Cheddar cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(6) Good Manufacturing Practice in accordance with the requirements of sections B.08.033, B.08.034, B.08.037, B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3, B.08.041.4, B.8.041.5, B.08.041.6, B.08.041.7 and B.08.041.8
18-10-79 10-6-82			

*(R) Minor correction

TABLE III - (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
25-7-84	1	(continued)	(7) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(7) Good Manufacturing Practice
10-12-92			(8) Longaniza; Tocino	(8) 0.1% in accordance with the requirements of paragraph B.14.031(i) or subparagraph B.14.032(d)(xvi)
11-2-99			(9) Edible collagen film (iron oxide only)	(9) Good Manufacturing Practice
13-4-00			(10) Sausage casings (annatto only)	(10) 1.0% (Residues of annatto in sausage prepared with such casings not to exceed 100 p.p.m.)
			(11) Sausage casings (cochineal only)	(11) 0.75% (Residues of cochineal in sausage prepared with such casings not to exceed 75 p.p.m.)
	1A	β-apo-8'-Carotenal Ethyl β-apo-8'-carotenoate	(1) Apple (or rhubarb) and (naming the fruit) jam; Bread; Butter; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin; Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Liqueurs and alcoholic cordials; Margarine; (naming the flavour) milk; Pickles and relishes; Pineapple marmalade with pectin; Sherbet; (naming the flavour) skimmed milk; (naming the flavour) partly skimmed milk; (naming the flavour) skim milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Tomato catsup	(1) 35 p.p.m.
6-4-89 17-11-77 13-5-85			(2) Unstandardized foods	(2) 35 p.p.m.

*(R) Minor correction

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
1A	(continued)	(3) (named variety) Cheese; Cheddar cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-packcheese food; Cold-pack cheese food with (named added ingredients)	(3) 35 p.p.m., in accordance with the requirements of sections B.08.033, B.08.034, B.08.037, B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3, B.08.041.4, B.08.041.5, B.08.041.6, B.008.041.7 and B.08.041.8
25-7-84		(4) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(4) 35 p.p.m.
2	Caramel	(1) Ale; Apple (or rhubarb) and (naming the fruit) jam; Beer; Brandy; Bread; Brown bread; Butter; Cider; Cider vinegar; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin; Holland's gin; Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Light beer; Liqueurs and alcoholic cordials; Malt liquor; Malt vinegar; (naming the flavour) Milk; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; Porter; Rum; Sherbet; (naming the flavour) skim milk; (naming the flavour partly skimmed milk; (naming the flavour) skim milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Stout; Tomato catsup; Whisky; Wine; Wine vinegar; Honey wine	(1) Good Manufacturing Practice
6-4-89 25-8-76 25-7-84			

*(R) Minor correction

TABLE III - (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
25-7-84	2	(continued)	(2) Unstandardized foods	(2) Good Manufacturing Practice
			(3) A blend of prepared meat referred to in paragraph B.21.006(n)	(3) Good Manufacturing Practice
13-4-00			(4) Sausage casings	(4) 15% (residues of caramel in sausage prepared with such casings not to exceed 0.15%)
	3	Allura Red Amaranth Erythrosine Indigotine Sunset Yellow FCF Tartrazine	(1) Apple (or rhubarb) and (naming the fruit) jam; Bread; Butter; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin; Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; naming the fruit) jelly with pectin; Liqueurs and alcoholic cordials; (naming the flavour) milk; Pickles and relishes; Pineapple marmalade with pectin; Sherbet; (naming the flavour skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) skim Milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Tomato catsup	(1) 300 p.p.m. singly or in combination in accordance with Section B.06.002.
7-6-84				
6-4-89				
13-5-75				
26-6-80				
25-7-84			(2) Unstandardized foods	(2) 300 p.p.m. singly or in combination in accordance with Section B.06.002.
			(3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(3) 300 p.p.m. singly or in combination in accordance with Section B.06.002
17-10-95			(4) Salted anchovy, salted scad and salted shrimp	(4) 125 p.p.m. in accordance with the requirements of paragraph B.21.021(d)
			(5) Longaniza	(5) 80 p.p.m. allura red in accordance with the requirements of clause B.14.032*(d)(xvi)*(B) and 20 p.p.m. sunset yellow FCF in accordance with the requirements of clause B.14.032*(d)(xvi)*(C)
20-11-97				
13-4-00			(6) Sausage casings (sunset yellow FCF only)	(6) 0.15% (Residues of sunset yellow FCF in sausage prepared with such casings not to exceed 15 p.p.m.)

*(R) Minor correction

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
13-5-75	4	Brilliant Blue FCF Fast Green FCF	(1) Apple (or rhubarb and (naming the fruit) jam; Bread; Butter; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin; Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Liqueurs and alcoholic cordials; (naming the flavour) milk; Pickles and relishes; Pineapple marmalade with pectin; Sherbet; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) skim milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Tomato catsup	(1) 100 p.p.m. singly or in combination in accordance with Section B.06.002.
6-4-89 26-6-80			(2) Unstandardized foods	(2) 100 p.p.m. singly or in combination in accordance with Section B.06.002.
25-7-84			(3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(3) 100 p.p.m. singly or in combination in accordance with Section B.06.002.
10-2-00			(4) Feta cheese (brilliant blue FCF only)	(4) 0.10 p.p.m.
	5	Citrus Red No. 2	Skins of whole oranges	2 p.p.m.
28-9-67	6	Ponceau SX	Fruit Peel; Glacé fruits; Maraschino cherries	150 p.p.m.
30-8-95	7	Gold	Alcoholic beverages	Good Manufacturing Practice

*(R) Minor correction

TABLE IV
FOOD ADDITIVES THAT MAY BE USED AS EMULSIFYING, GELLING, STABILIZING AND THICKENING AGENTS

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
11-5-06	A.1	Acacia Gum	(1) Cream; French dressing; (naming the flavour) Milk; Mustard pickles; (naming the flavour) Partly skimmed milk; (naming the flavour) Partly skimmed milk with added milk solids; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Skim milk with added milk solids;	(1) Good Manufacturing Practice
18-10-79			(2) Ice cream; Ice cream mix; Ice Milk; Ice milk mix	(2) 0.5%
			(3) Sherbet	(3) 0.75%
			(4) Unstandardized foods	(4) Good Manufacturing Practice
17-11-77			(5) Calorie-reduced margarine	(5) 0.5% in accordance with the requirements of section B.09.017
13-9-79			(6) Canned asparagus; Canned green beans; Canned wax beans; Canned peas	(6) 1.0% in accordance with the requirements of clause B.11.002(d)(viii)(C)
	A.2	Acetylated Mono-glycerides	Unstandardized foods	Good Manufacturing Practice
1-4-82	A.3	Acetylated Tartaric Acid Esters of Mono- and Diglycerides	(1) Bread	(1) 6,000 p.p.m. of flour
			(2) Unstandardized foods	(2) Good Manufacturing Practice
19-11-96			(3) Infant formulas based on crystalline amino acids	(3) 240 p.p.m. as consumed

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
13-5-75	A.4	Agar	(1) Brawn; Canned (naming the poultry); Cream; Headcheese; (naming the fruit) Jelly with pectin; Meat binder (when sold for use in prepared meat or meat by-products in which a gelling agent is a permitted ingredient); Meat by-product loaf; Meat loaf; (naming the flavour) Milk; Mustard pickles; Potted meat; Potted meat by-product; Prepared fish or prepared meat (Division 21); Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids	(1) Good Manufacturing Practice
18-10-79		(2) Ice cream; Ice cream mix; Ice milk; Ice milk mix	(2) 0.5%
		(3) Sherbet	(3) 0.75%
		(4) Unstandardized foods	(4) Good Manufacturing Practice
17-11-77		(5) Calorie-reduced margarine	(5) 0.5% in accordance with the requirements of Section B.09.017

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
A.5	Algin	(1) Ale; Beer; Cream; French dressing; Light beer; Malt liquor; (naming the flavour) Milk; Mustard pickles; Porter; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids; Stout	(1) Good Manufacturing Practice
18-10-79 28-11-05		(2) Infant formula	(2) 0.3% as consumed. If used in combination with carrageenan or guar gum or both, the total not to exceed 0.03%
10-11-76		(3) Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix	(3) 0.5%
		(4) Sherbet	(4) 0.75%
17-11-77		(5) Unstandardized foods	(5) Good Manufacturing Practice
16-11-78		(6) Calorie-reduced margarine	(6) 0.5% in accordance with the requirements of Section B.09.017.
13-9-79		(7) Sour Cream	(7) 0.5% in accordance with the requirements of clause B.08.077(*b*)(viii)(A)
28-11-05		(8) Canned asparagus; Canned green beans; Canned wax beans; Canned peas	(8) 1.0% in accordance with the requirements of clause B.11.002(*d*)viiii)(C)
		(9) Infant formula based on isolated amino acids or protein hydrolysates, or both	(9) 0.1% as consumed. If used in combination with carrageenan or guar gum or both, the total not to exceed 0.1%
		(10) Lactose-free infant formula based on milk protein	(10) 0.05% as consumed. If used in combination with carrageenan or guar gum or both, the total not to exceed 0.05%
A.6	Alginic Acid	Same foods as listed for Algin	Same levels as prescribed for Algin.
A.7	Ammonium Alginate	Same foods as listed for Algin	Same levels as prescribed for Algin.
2-5-72 A.8	Ammonium Carrageenan	Same foods as listed for Carrageenan.	Same levels as prescribed for Carrageenan.
15-6-67 A.9	Ammonium Furcelleran	Same foods as listed for Furcelleran.	Same level as prescribed for Furcelleran.

TABLE IV -- (continued)

	Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
13-5-75	A.9A	Ammonium Salt of Phosphorylated Glyceride	(1) Bread; Cream; (naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids	(1) Good Manufacturing Practice
20-5-97			(2) Ice cream; Ice cream mix; Ice milk; Ice milk mix	(2) 0.5%
			(3) Sherbet	(3) 0.75%
			(4) Unstandardized foods	(4) Good Manufacturing Practice
			(5) Chocolate products; Cocoa products	(5) 0.7%
15-9-77	A.10	Arabino-galactan	Essential Oils; unstandardized dressing; pudding mixes; beverage bases and mixes; pie filling mixes	Good Manufacturing Practice
3-9-74	B.1	Baker's yeast Glycan	Unstandardized Foods	Good Manufacturing Practice

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
C.1	Calcium Alginate	Same foods as listed for Algin	Same levels as prescribed for Algin
C.2	Calcium Carbonate	(1) Unstandardized foods (2) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
C.3	Calcium Carrageenan	Same foods as listed for carrageenan	Same levels as prescribed for Carrageenan
C.4	Calcium Citrate	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (name added ingredients) (2) Unstandardized foods	(1) 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 (2) Good Manufacturing Practice
C.5	Calcium Furcelleran	Same foods as listed for Furcelleran	Same levels as prescribed for Furcelleran
C.6	Calcium Gluconate	Unstandardized foods	Good Manufacturing Practice
C.7	Calcium Glycero-Phosphate	Unstandardized dessert mixes	Good Manufacturing Practice
C.8	Calcium Hypophosphite	Unstandardized dessert mixes	Good Manufacturing Practice
C.9	Calcium Phosphate, Dibasic	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients) (2) Unstandardized foods	(1) 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 (2) Good Manufacturing Practice

4-6-92

2-5-72

18-10-79

18-10-79

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
C.10	Calcium Phosphate, Tribasic	Unstandardized foods	Good Manufacturing Practice
C.11	Calcium Sulphate	(1) Ice cream; Ice cream mix; Ice milk; Ice milk mix (2) Sherbet (3) Unstandardized foods (4) Creamed cottage cheese (5) Cream for whipping, heat-treated above 100°C	(1) 0.5% (2) 0.75% (3) Good Manufacturing Practice (4) 0.5% (5) 0.005%
11-8-88			
13-5-75 C.12	Calcium Tartrate	Unstandardized foods	Good Manufacturing Practice
C.13	Carboxy-methyl Cellulose	Same foods as listed for Sodium Carboxymethyl Cellulose	Same levels as prescribed for Sodium Carboxymethyl Cellulose
C.14	Carob Bean Gum	(1) Cream; French dressing; (naming the flavour) Milk; Mustard pickles; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed Milk; (naming the flavour) Skim Milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids	(1) Good Manufacturing Practice
16-11-78 18-10-79			
		(2) Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix	(2) 0.5%
		(3) Calorie-reduced margarine	(3) 0.5%, in accordance with the requirements of paragraph B.09.017(b)
		(4) Sherbet	(4) 0.75%
16-11-78		(5) Sour cream	(5) 0.5%, in accordance with the requirements of clause B.08.077(b)(vii(A)
		(6) Unstandardized foods	(6) Good Manufacturing Practice
		(7) Cream cheese; Cream cheese with (name added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(7) 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6 B.08.041.7 and B.08.041.8
2-12-82			

*(R) Minor correction

TABLE IV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
18-10-79	C.15	Carrageenan	(1) Ale; Beer; Brawn; Canned (naming the poultry); Cream; French dressing; Headcheese; (naming the fruit) Jelly with pectin; Light beer; Malt liquor; Meat binder (when sold for use in prepared meat or prepared meat by-products in which a gelling agent is a permitted ingredient); Meat by-product loaf; Meat loaf; (naming the flavour) Milk; Mustard pickles; Porter; Potted meat; Potted meat by-product; Prepared fish or prepared meat (Division 21); Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids; Stout	(1) Good Manufacturing Practice
13-5-75			(2) Cottage cheese; Creamed cottage cheese; Ice cream, Ice cream mix; Ice milk, Ice milk mix	(2) 0.5%
17-11-77			(3) Evaporated Milk	(3) 0.015%
			(4) Sherbet	(4) 0.75%
			(5) Evaporated partly skimmed milk; concentrated partly skimmed milk	(5) 0.01%
16-11-78			(6) Infant formula based on isolated amino acids or protein hydrolysates, or both	(6) 0.1% as consumed. If used in combination with algin or guar gum or both, the total not to exceed 0.1%
			(7) Infant formula	(7) 0.03% as consumed. If used in combination with algin or guar gum or both, the total not to exceed 0.03%
			(8) Unstandardized foods	(8) Good Manufacturing Practice
			(9) Calorie-reduced margarine	(9) 0.5% in accordance with the requirements of section B.09.017
			(10) Sour Cream	(10) 0.5%, in accordance with the requirements of clause B.08.077(b)(vii)(A)
13-9-79			(11) Canned asparagus; Canned green beans; Canned wax beans; Canned peas.	(11) 1.0%, in accordance with the requirements of clause B.11.002(d)(viii(C)

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
C.15	Carrageenan -- cont'd	(12) Cream cheese; cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(12) 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4 B.08.041.6, B.08.041.7 and B.08.041.8
2-12-82			
28-11-05		(13) Lactose-free infant formula based on milk protein	(13) 0.05% as consumed. If used in combination with algin or guar gum or both, the total not to exceed 0.05%
C.17	Cellulose Gum	Same foods as listed for Sodium Carboxymethyl Cellulose	Same level as prescribed for Sodium Carboxymethyl Cellulose.
F.1	Furcelleran	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout	(1) Good Manufacturing Practice
16-11-71		(2) Unstandardized foods	(2) Good Manufacturing Practice
		(3) Calorie-reduced margarine	(3) 0.5% in accordance with the requirements of section B.09.017.
17-11-77			
		(4) Canned asparagus; Canned green beans; Canned wax beans; Canned peas	(4) 1.0% in accordance with the requirements of clause B.11.002(d)(viii)(C)
13-9-79			

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
G.1	Gelatin	(1) Brawn; Canned (naming the poultry); Cream; Headcheese; (naming the fruit) Jelly with pectin; Meat binder (when sold for use in prepared meat by-products in which a gelling agent is a permitted ingredient); Meat by-product loaf; Meat Loaf; (naming the flavour) Milk; Mustard pickles; Potted meat; Potted meat by-product; Prepared fish or prepared meat (Division 21); Prepared hams, shoulders, butts and picnics; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids	(1) Good Manufacturing Practice
13-5-75		(2) Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix	(2) 0.5%
18-10-79		(3) Sherbet	(3) 0.75%
		(4) Sour cream	(4) 0.5% in accordance with the requirements of clause B.08.077(b)(vii(A)
		(5) Unstandardized Foods	(5) Good Manufacturing Practice
16-11-78		(6) Cream cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(6) 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4 B.08.041.6, B.08.041.7 and B.08.041.8
8-12-83			

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
G.2	Gellan Gum	(1) Confectionery; Frostings; (except for any of these products for which standards are set out in these Regulations)	(1) 0.5%
13-1-94		(2) Fruit spreads; Aspic; Processed fruit products; (except for any of these products for which standards are set out in these Regulations)	(2) 0.3%
		(3) Calorie-reduced margarine; Reduced fat spreads	(3) 0.25%
		(4) Dairy products (except for any of these products for which standards are set out in these Regulations)	(4) 0.15%
		(5) French Dressing; Salad Dressing; Dressings (except for any of these products for which standards are set out in these Regulations); Gelatins; Puddings; Fillings	(5) 0.1%
		(6) Baking mixes; Bakery products; (except for any of these products for which standards are set out in these Regulations)	(6) 0.1% of the dry mix
		(7) Sauces, Toppings; Table syrups; (except for any of these products for which standards are set in these Regulations)	(7) 0.05%
		(8) Beverages (except for any of these products for which standards are set out in these Regulations)	(8) 0.08%
19-12-96		(9) Snack foods (except for any of these products for which standards are set out in these Regulations)	(9) 0.1%

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	G.3 Guar Gum	(1) Cream; French dressing; (naming the flavour) Milk; Mince meat; Mustard pickles; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids	(1) Good Manufacturing Practice
13-5-75 18-10-79		(2) Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice Milk, Ice milk mix	(2) 0.5%
10-11-76 17-11-77 16-11-78		(3) Infant formula	(3) 0.03% as consumed. If used in combination with algin or carrageenan or both the total not to exceed 0.03%.
		(4) Sherbet	(4) 0.75%
		(5) Unstandardized foods	(5) Good Manufacturing Practice
		(6) Calorie-reduced margarine	(6) 0.5% in accordance with the requirements of section B.09.017.
2-12-82		(7) Sour cream	(7) 0.5% in accordance with the requirements of clause B.08.077(b)(vii)(A)
		(8) Canned asparagus; Canned green beans; Canned wax beans; Canned peas	(8) 1.0% in accordance with the requirements of clause B.11.002(d)(viii)(C)
		(9) Cream cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(9) 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8
28-11-05		(10) Infant formula based on isolated amino acids or protein hydrolysates, or both	(10) 0.1% as consumed. If used in combination with algin or carrageenan or both, the total not to exceed 0.1%
		(11) Lactose-free infant formula based on milk protein	(11) 0.05% as consumed. If used in combination with algin or carrageenan or both, the total not to exceed 0.05%
	G.4 Gum Arabic	Same foods as listed for Acacia Gum	Same level as prescribed for Acacia Gum.

TABLE IV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
20-5-97 23-6-71	H.1	Hydroxylated Lecithin	(1) Chocolate products; Cocoa products (2) Unstandardized foods	(1) 1.0% (2) Good Manufacturing Practice
26-11-69	H.1A	Hydroxypropyl cellulose	Unstandardized foods	Good Manufacturing Practice
13-5-75	H.2	Hydroxypropyl Methyl-cellulose	(1) French dressing; (naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids; Salad dressing (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
2-5-72	I.1	Irish Moss Gelose	Same foods as listed for Carrageenan	Sames levels as prescribed for Carrageenan
13-5-75 18-10-79 17-11-77	K.1	Karaya gum	(1) French dressing; (naming the flavour) Milk; Mustard pickles, Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids; Salad dressing (2) Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix (3) Sherbet (4) Unstandardized foods (5) Calorie-reduced margarine	(1) Good Manufacturing Practice (2) 0.5% (3) 0.75% (4) Good Manufacturing Practice (5) 0.5% in accordance with the requirements of Section B.09.017
	L.1	Lactylated Mono- and Di-glycerides	(1) Shortening (2) Unstandardized Foods	(1) 8.0% (except that the total combined mono- and di-glycerides and lactylated mono- and di-glycerides must not exceed 20.0% of the shortening). (2) 8.0% of the fat content
25-3-65	L.1A	Lactylic Esters of Fatty Acids	Unstandardized Foods	Good Manufacturing Practice

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	L.2	Lecithin	(1) Bread; Cream; (naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids	(1) Good Manufacturing Practice
13-5-75				
20-5-97			(2) Ice cream; Ice cream mix; Ice milk; Ice milk mix	(2) 0.5%, singly or in combination with other emulsifiers
			(3) Infant formula	(3) 0.3% as consumed
			(4) Sherbet	(4) 0.75%
17-11-77			(5) Unstandardized foods	(5) Good Manufacturing Practice
			(6) Margarine	(6) 0.2%
			(7) Calorie-reduced margarine	(7) 0.5%
			(8) Processed (named variety) cheese; Processed (named variety) cheese with (name added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(8) 0.2%
18-10-79				
8-12-83				
			(9) Milk Powder	(9) 0.5%
20-5-97			(10) Chocolate products; Cocoa products	(10) 1.0%
	L.3	Locust Bean Gum	Same foods as listed for Carob Bean Gum	Same levels as prescribed for Carob Bean Gum
9-7-81	M.1	Magnesium Chloride	Tofu	0.3%, calculated as the anhydrous salt.
9-7-81	M.2	Methylcellulose	(1) Ale; Beer; French dressing; Light beer; Malt liquor; Porter; Salad dressing; Stout	(1) Good Manufacturing Practice
18-10-79			(2) Unstandardized foods	(2) Good Manufacturing Practice
9-7-81 27-6-85	M.3	Methyl Ethyl Cellulose	Unstandardized foods	Good Manufacturing Practice

*(R) Minor correction

TABLE IV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
9-7-81 20-5-97	M.4	Mono-glycerides	(1) Bread; Cream; Fish paste	(1) Good Manufacturing Practice
			(2) Chocolate products; Cocoa products	(2) 1.5%
20-5-97			(3) Ice cream mix; Ice milk mix	(3) A total of 0.5% of stabilizing agents in accordance with subparagraphs B.08.061(b)(vi) and B.08.071(b)(vi)
			(4) Creamed cottage cheese	(4) Good Manufacturing Practice
			(5) Infant formula	(5) 0.25% as consumed
			(6) Sausage casings	(6) 0.35% of the casing
			(7) Margarine	(7) 0.5%
			(8) Sherbet	(8) 0.75%
23-9-93			(9) Shortening	(9) 10.0% (except that the total combined mono and diglycerides and lactylated mono and diglycerides must not exceed 20.0% of the shortening)
8-1-81			(10) Sour Cream	(10) 0.3%
			(11) Unstandardized Foods	(11) Good Manufacturing Practice
			(12) Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(12) 0.5% in accordance with the requirements of sections B.08.040, B.08.041, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3, and B.08.041.4

*(R) Minor correction

TABLE IV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
9-7-81 20-5-97	M.5	Mono- and Diglycerides	(1) Bread; Cream; Fish paste	(1) Good Manufacturing Practice
			(2) Chocolate products; Cocoa products	(2) 1.5%
			(3) Ice cream mix; Ice milk mix	(3) A total of 0.5% of stabilizing agents in accordance with subparagraphs B.08.061(*b*)(*vi*) and B.08.071(*b*)(*vi*)
			(4) Cottage Cheese; Creamed Cottage Cheese	(4) Good Manufacturing Practice
23-1-92			(5) Infant formula	(5) 0.25% as consumed
			(6) Sausage casings	(6) 0.35% of the casing
23-9-93			(7) Margarine	(7) 0.5%
			(8) Sherbet	(8) 0.75%
			(9) Shortening	(9) 10.0% (except that the total combined mono- and diglycerides and lactylated mono- and diglycerides must not exceed 20.0% of the shortening.)
			(10) Sour Cream	(10) 0.3%
			(11) Unstandardized Foods	(11) Good Manufacturing Practice
			(12) Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(12) 0.5% in accordance with the requirements of sections B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4
19-11-96	M.6	Monosodium Salts of Phosphorylated Mono- and Diglycerides	(1) Edible vegetable oil-based cookware coating emulsions	(1) 4.0%
18-10-79	0.1	Oat Gum	(1) Unstandardized foods	(1) Good Manufacturing Practice

*(R) Minor correction

TABLE IV -- (continued)

Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
P.1	Pectin	(1) Apple (or rhubarb) and (naming the fruit) Jam; Cream; Fig marmalade; Fig marmalade with pectin; French dressing; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade with pectin; (naming the flavour) Milk; Mince meat; Mustard pickles; Pineapple marmalade; Pineapple marmalade with pectin; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk); (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids	(1) Good Manufacturing Practice
		(2) Ice cream; Ice cream mix; Ice milk; Ice milk mix	(2) 0.5%
		(3) Sour cream	(3) 0.5% in accordance with the requirement of clause B.08.077(*b*)(viii)(A)
		(4) Sherbet	(4) 0.75%
		(5) Unstandardized foods	(5) Good Manufacturing Practice

8-1-81

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
14-2-85 19-3-96	P.1A Polyglycerol Esters of Fatty Acids	(1) Unstandardized Foods (2) Vegetable Oils (3) Calorie-reduced margarine	(1) Good Manufacturing Practice (2) 0.025% (3) 0.2% in accordance with the requirements of paragraph B.09.017(c)
20-5-97 23-6-71 26-6-80 14-1-88	P.1B Polyglycerol Esters of Interesterified Castor Oil Fatty Acids	(1) Chocolate products (2) Unstandardized chocolate flavoured confectionery coatings (3) Edible vegetable oil-based pan coating emulsions for use on baking pans	(1) 0.5% (2) 0.25% (3) 2.0%
23-1-74 13-5-75 5-4-77 27-4-78	P.2 Polyoxyethylene (20) Sorbitan Monooleate; Polysorbate 80	(1) Ice cream; Ice cream mix; Ice milk; Ice milk mix; Sherbet (2) Unstandardized frozen desserts (3) Pickles and relishes (4) Beverage base or mix (5) Imitation dry cream mix (6) Whipped vegetable oil topping (7) Cake icing; Cake icing mix (8) Salt (9) Whipped cream (10) Breath freshener products in candy, tablet or gum form (11) Creamed cottage cheese (12) Spice oils and spice oleoresins for use in pumping pickle employed in the curing of preserved meat or preserved meat by-product (Division 14)	(1) 0.1%. If Polyoxyethylene (20) Sorbitan Tristearate is also used, the total must not exceed 0.1% (2) 0.1% (3) 0.05% (4) 0.05% of the beverage. If Sorbitan Monostearate is also used the total must not exceed 0.05% of the beverage (5) 0.1%. If Polyoxyethylene (20) sorbitan monostearate, Polyoxyethylene (20) sorbitan tristearate or Sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.4% (6) 0.05%. If Polyoxyethylene (20) sorbitan monostearate, Polyoxyethylene (20) sorbitan tristearate or Sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.4% (7) 0.5% of the finished cake icing. If Polyoxyethylene (20) sorbitan monostearate, or Sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.5% of the finished cake icing (8) 10 parts per million (9) 0.1% (10) 100 p.p.m. (11) 80 p.p.m (12) 0.2% of the pumping pickle

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
12-11-81 11-10-84 14-2-85 5-12-91 16-8-94 7-10-96	P.2 Polyoxyethylene (20) Sorbitan Monooleate; Polysorbate 80 (Conc.)	(13) Sausage casings (14) Liquid Smoke Flavours (15) Vegetable oils (16) Annatto formulations (17) Turmeric formulations (18) Liquid smoke flavour concentrate (19) Unstandardized salad dressing	(13) 0.15% of the casing (14) Good Manufacturing Practice. Residues of Polysorbate 80 must not exceed 275 ppm in the finished food (15) 0.125% (16) 25% of the total colour formulation (17) 50% of the total colour formulation (18) Good Manufacturing Practice. Residues of Polysorbate 80 must not exceed 0.3% in the finished food. (19) 0.25%
1-10-68	P.3 Polyoxyethylene (20) Sorbitan Monostearate; Polysorbate 60	(1) Imitation dry cream mix; Vegetable oil creaming agent; Whipped vegetable oil topping; Vegetable oil topping mix (2) Cakes (3) Cakes; Cake mixes	(1) 0.4%. If Polyoxyethylene (20) sorbitan tristearate, Sorbitan monostearate or Polyoxyethylene (20) sorbitan monooleate, either singly or in combination is also used, the total must not exceed 0.4%, except that in the case of whipped vegetable oil topping a combination of Polysorbate 60 and Sorbitan monostearate may be used in excess of 0.4%, if the amount of the Polysorbate 60 does not exceed 0.77% and the amount of Sorbitan monostearate does not exceed 0.27% of the whipped vegetable oil topping (2) 0.5% on a dry weight basis. If Polyoxyethylene (20) Sorbitan Tristearate is also used, the total must not exceed 0.5% on a dry weight basis (3) 0.5% on a dry weight basis. If Sorbitan Monostearate is also used, the total must not exceed 0.7% on a dry weight basis

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
26-6-80	P.3 Polyoxyethylene (20) Sorbitan Monostearate; Polysorbate 60 (cont'd)	(4) Unstandardized confectionery coatings and unstandardized moulded confectionery products for use as confectionery or in baking	(4) 0.5%. If any combination of Polyoxyethylene (20) Sorbitan tristearate, Sorbitan monostearate or Sorbitan tristearate are also used, the total must not exceed 1.0%
		(5) Cake icing; Cake icing mix	(5) 0.5% of the finished cake icing. If Sorbitan monostearate or Polyoxyethylene (20) sorbitan monooleate either singly or in combination is also used, the total must not exceed 0.5% of the finished cake icing.
		(6) Pudding; Pie filling	(6) 0.5% on a dry weight basis.
		(7) Beverage base or mix	(7) 0.05% of the beverage. If Sorbitan monostearate is also used the total must not exceed 0.05% of the beverage.
25-2-69		(8) Sour Cream Substitute	(8) 0.1%
24-8-72		(9) Unstandardized dressings; Unstandardized prepared canned cooking sauces	(9) 0.3%
13-8-69		(10) Fat base formulation for self-basting of poultry by injection	(10) 0.25%
27-3-73		(11) Unstandardized spreads and dips	(11) 0.2%
23-1-74		(12) Dry soup base or mix	(12) 250 p.p.m. in soup as prepared for consumption.
		(13) Dry batter coating mixes	(13) 0.5% of the dry mix.
12-11-81		(14) Prepared alcoholic cocktails	(14) 120 p.p.m. in beverage as prepared for consumption.

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
P.4 27-4-78 13-5-75	Polyoxyethylene (20) Sorbitan Tristearate; Polysorbate 65	(1) (naming the flavour) Milk; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids	(1) 0.5%
		(2) Ice cream; Ice cream mix; Ice milk; Ice milk mix; Sherbet	(2) 0.1%. If Polyoxyethylene (20) Sorbitan Monooleate is also used, the total must not exceed 0.1%.
		(3) Unstandardized frozen desserts	(3) 0.1%
		(4) Cakes	(4) 0.3% on a dry weight basis. If Polyoxyethylene (20) Sorbitan Monostearate is also used, the total must not exceed 0.5% on a dry weight basis.
23-1-74		(5) Unstandardized confectionery coatings	(5) 0.5%. If any combination of Polyoxyethylene (20) Sorbitan monostearate, Sorbitan monostearate, or Sorbitan tristearate are also used, the total must not exceed 1.0%.
		(6) Beverage base or mix	(6) 0.05% of the beverage. If Sorbitan Monostearate is also used, the total must not exceed 0.5% of the beverage.
		(7) Imitation dry cream mix; Vegetable oil creaming agent; Whipped vegetable oil topping; Vegetable oil topping mix	(7) 0.4%. If Polyoxyethylene (20) sorbitan monostearate, Sorbitan monostearate or Polyoxyethylene (20) sorbitan monooleate, either singly or in combination is also used, the total must not exceed 0.4%.
		(8) Breath freshener products in candy, tablet or gum form	(8) 200 p.p.m.

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
P.5	Polyoxy-ethylene (8) Stearate	Unstandardized bakery foods	0.4%
P.6	Potassium Alginate	Same foods as listed for Algin	Same levels as prescribed for Algin.
P.7 2-9-72	Potassium Carrageenan	Same foods as listed for Carrageenan	Same levels as prescribed for Carrageenan
P.8	Potassium Chloride	Unstandardized foods	Good Manufacturing Practice
P.9 18-10-79	Potassium Citrate	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed(named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(1) 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4
P.10	Potassium Furcelleran	Same foods as listed for Furcelleran	Same levels as prescribed for Furcelleran.
P.11 18-11-79	Potassium Phosphate, dibasic	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(1) 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4
P.12 16-11-71 18-10-79	Propylene Glycol Alginate	(1) Ale; Beer; French dressing; Light beer; Malt liquor; Mustard pickles; Porter; Relishes; Salad dressing; Stout (2) Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix (3) Sherbet	(1) Good Manufacturing Practice (2) 0.5% (3) 0.75%

*(R) Minor correction

TABLE IV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
17-11-77 16-11-78	P.12	Propylene Glycol Alginate (cont'd.)	(4) Unstandardized foods (5) Calorie-reduced margarine (6) Sour cream (7) Canned asparagus; Canned green beans; Canned wax beans; Canned Peas (8) Cream cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(4) Good Manufacturing Practice (5) 0.5% in accordance with the requirements of section B.09.017 (6) 0.5% in accordance with the requirements of clause B.08.077(b)(vii)(A) (7) 1.0% in accordance with the requirements of clause B.11.002(d)(viii)(C) (8) 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.040, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8
2-12-82	P.13	Propylene Glycol Ether of Methylcellulose	Same foods as listed for Hydroxypropyl Methylcellulose	Same levels as prescribed for Hydroxypropyl Methylcellulose
15-5-68	P.14	Propylene Glycol mono Fatty Acid Esters	Unstandardized foods	Good Manufacturing Practice
18-10-79	S.1	Sodium Acid Pyrophosphate	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(1) 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4
17-7-75	S.2	Sodium Alginate	(1) Same foods as listed for Algin (2) Coarse crystal salt (3) Glaze of frozen fish	(1) Same levels as prescribed for Algin (2) 15 p.p.m. (3) Good Manufacturing Practice

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
S.2A	Sodium Aluminum Phosphate	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(1) 3.5% in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4
S.3 13-5-75 18-10-79	Sodium Carboxy-methyl Cellulose	(1) Cream; French dressing; (naming the flavour) Milk; Mustard pickles; Relishes; Salad dressing; (naming the flavour) Skim Milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids.	(1) Good Manufacturing Practice
		(2) Cottage cheese; creamed cottage cheese; Ice cream, Ice cream mix; Ice milk; Ice milk mix	(2) 0.5%
17-7-75		(3) Sherbet	(3) 0.75%
		(4) Unstandardized foods	(4) Good Manufacturing Practice
		(5) Glaze of frozen fish	(5) Good Manufacturing Practice
2-12-82		(6) Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients)	(6) 0.5%
		(7) Cream cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) Cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(7) 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
2-5-72 S.4	Sodium Carrageenan	Same foods as listed for Carrageenan	Same levels as prescribed for Carrageenan.
S.5	Sodium Cellulose Glycolate	Same foods as listed for Sodium Carboxymethyl Cellulose	Same levels as prescribed for Sodium Carboxymethyl Cellulose.
S.6	Sodium Citrate	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(1) 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3, and B.08.041.4
18-10-79		(2) Evaporated milk; evaporated skim milk or concentrated skim milk; evaporated partly skimmed milk or concentrated partly skimmed milk	(2) 0.1% singly or in combination with sodium phosphate, dibasic.
16-8-78 4-10-73		(3) Ice cream; Ice cream mix; Ice milk; Ice milk mix	(3) 0.5%
		(4) Sherbet	(4) 0.75%
S.7	Sodium Furcelleran	Same food as listed for Furcelleran	Same levels as prescribed for Furcelleran.
S.8	Sodium Gluconate	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (name added ingredients)	(1) 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4
18-10-79			

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
18-10-79 10-11-76 18-10-79 25-7-84	S.9	Sodium Hexameta-phosphate	(1) Mustard Pickles; Relishes (2) Ice cream; Ice cream mix; Ice milk; Ice milk mix (3) Infant formula (4) Sherbet (5) Unstandardized foods (6) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients) (7) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(1) Good Manufacturing Practice (2) 0.5% (3) 0.05% as consumed (4) 0.75% (5) Good manufacturing Practice (6) 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 (7) 0.1%
	S.11	Sodium Phosphate, dibasic	(1) (naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Skim Milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids (2) Cottage cheese; Creamed cottage cheese (3) Evaporated milk; evaporated skim milk or concentrated skim milk; evaporated partly skimmed milk or concentrated partly skimmed milk (4) Sour cream (5) Unstandardized Foods (6) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(1) Good Manufacturing Practice (2) 0.5% (3) 0.1% singly or in combination with sodium citrate (4) 0.05% in accordance with the requirements of clause B.08.077(b)(vii)(C) (5) Good Manufacturing Practice (6) 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
S.12 18-10-79	Sodium Phosphate, monobasic	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients) (2) Unstandardized foods	(1) 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 (2) Good Manufacturing Practice
S.13 18-10-79	Sodium Phosphate, tribasic	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients) (2) Unstandardized foods	(1) 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 (2) Good Manufacturing Practice
S.14 18-10-79	Sodium Potassium Tartrate	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients) (2) Unstandardized foods	(1) 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 (2) Good Manufacturing Practice

*(R) Minor correction

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
S.15	Sodium Pyro-phosphate, tetrabasic	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(1) 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4
18-10-79		(2) Unstandardized foods	(2) Good Manufacturing Practice
		(3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(3) 0.1%
25-7-84			

TABLE IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
25-10-05 5-11-74 18-1-90 25-10-05	S.15A Sodium Stearoyl-2-Lactylate	(1) Icing and icing mixes (2) Fillings and filling mixes (3) Puddings and pudding mixes (4) Sour cream substitutes (5) Vegetable oil creaming agents (6) Batter mix (7) Unstandardized cream-based liquors (8) Salad dressing; French dressing (9) Soups	(1) 0.4% of dry ingredient weight (2) 0.5% of dry ingredient weight (3) 0.2% of the finished product (4) 1.0% of dry ingredient weight (5) 2.0% of dry ingredient weight (6) 0.75% of dry ingredient weight (7) 0.35% of the finished product (8) 0.4% of the finished product (9) 0.2% of the finished product
23-1-74 18-10-79	S.16 Sodium Tartrate	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(1) 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041.2, B.08.041.3 and B.08.041.4
25-7-84	S.16A Sodium Tripoly-phosphate	A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	0.1%
1-10-68	S.18 Sorbitan Monostearate	(1) Imitation dry cream mix; Vegetable oil creaming agent; Whipped vegetable oil topping; Vegetable oil topping mix (2) Cake, Cake mix	(1) 0.4%. If Polyoxyethylene (20) sorbitan tristearate, Polysorbate 60 or Polyoxyethylene (20) sorbitan mono-oleate, either singly or in combination is also used, the total must not exceed 0.4%, except that in the case of whipped vegetable oil topping a combination of Sorbitan monostearate and Polysorbate 60 may be used in excess of 0.4%, if the amount of Sorbitan monostearate does not exceed 0.27% and the amount of Polysorbate 60 does not exceed 0.77% of the weight of the whipped vegetable oil topping (2) 0.6% on a dry weight basis. If Polyoxyethylene (20) Sorbitan Monostearate is also used, the total must not exceed 0.7% on a dry weight basis

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
23-1-74	S.18	Sorbitan Monostearate (cont'd.)	(3) Unstandardized confectionery coatings and unstandardized moulded confectionery products for use as confectionery or in baking	(3) 1.0%. If any combination of Polyoxyethylene (20) Sorbitan monostearate, Polyoxyethylene (20) Sorbitan tristearate or Sorbitan tristearate are also used, the total must not exceed 1.0%
26-6-80			(4) Cake icing; Cake icing mix	(4) 0.5% of the finished cake icing. If Polyoxyethylene (20) sorbitan monooleate or Polyoxyethylene (20) sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.5% of the finished cake icing
14-2-85			(5) Beverage base or mix	(5) 0.05% of the beverage. If Polyoxyethylene (20) Sorbitan Monooleate is also used, the total must not exceed 0.05% of the beverage. If Polyoxyethylene (20) Sorbitan Monostearate is also used, the total must not exceed 0.05% of the beverage. If Polyoxyethylene (20) Sorbitan Tristearate is also used, the total must not exceed 0.05% of the beverage
			(6) Dry soup base or mix	(6) 250 p.p.m. in soup as prepared for consumption
			(7) Dried yeast	(7) 1.5% (Residues of sorbitan monostearate in bread and other yeast leavened bakery products not to exceed 0.05%)
20-5-97			(8) Chocolate products	(8) 1.0%
12-11-81	S.18A	Sorbitan trioleate	Sausage casings	0.35% of the casing
	S.18B	Sorbitan tristearate	(1) Margarine; Shortening	(1) 1.0%
27-4-78			(2) Unstandardized confectionery coatings and unstandardized moulded confectionery products for use as a confectionery or in baking	(2) 1.0%. If any combination of Polyoxyethylene (20) Sorbitan monostearate, Polyoxyethylene (20) Sorbitan tristearate or Sorbitan monostearate are also used, the total must not exceed 1.0%
26-6-80				
	S.19	Stearyl Monoglyceridyl Citrate	Shortening	Good Manufacturing Practice
6-2-92	S.20	Sucrose esters of fatty acids	Carotenoid colour preparations	1.5%
11-5-06	T.2	Repealed by P.C. 2006-370 of May 11, 2006.		

TABLE IV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	T.3	Tragacanth Gum	(1) French dressing; Mustard pickles; Salad dressing; Relishes	(1) Good Manufacturing Practice
			(2) Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix	(2) 0.5%
			(3) Sherbet	(3) 0.75%
18-10-79			(4) Lumpfish Caviar	(4) 1.0%
24-8-72			(5) Unstandardized foods	(5) Good Manufacturing Practice
			(6) Calorie-reduced margarine	(6) 0.5% in accordance with the requirements of section B.09.017
17-11-77			(7) Cream cheese; Cream cheese with (name added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients)	(7) 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8
2-12-82				
10-12-74	X.1	Xanthan Gum	(1) French Dressing; Salad Dressing; Unstandardized foods	(1) Good Manufacturing Practice
18-10-79			(2) Cottage Cheese; Creamed Cottage Cheese	(2) 0.5% or, if used in combination with other stabilizing agents, the total amount of the combined stabilizers shall not exceed 0.5%
17-11-77			(3) Calorie-reduced margarine	(3) 0.5% in accordance with the requirements of section B.09.017
2-12-82			(4) Cream cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(4) 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8

*(R) Minor correction

TABLE IV - (concluded)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
8-1-81	X.1 Xanthan Gum (cont'd)	(5) Mustard Pickles; Relishes	(5) 0.1%
		(6) Ice Cream Mix	(6) 0.1% or, if used in combination with microcrystalline cellulose and other stabilizers, the total amount of combined stabilizers and microcrystalline cellulose shall not exceed 0.5%
9-7-81		(7) Ice Milk Mix	(7) 0.1% or, if used in combination with other stabilizers, the total amount of combined stabilizers shall not exceed 0.5%
		(8) Sherbet	(8) 0.1% or, if used in combination with other stabilizers, the total amount of combined stabilizers shall not exceed 0.75%
11-8-88		(9) Cream for whipping, heat-treated above 100°C	(9) 0.02%

*(R) Minor correction

TABLE V
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES

	Item No.	Column I Additive	Column II Permitted Source	Column III Permitted in or Upon	Column IV Maximum Level of Use
7-1-97	A.01	α-Acetolactate decarboxylase	*Bacillus subtilis* ToC46 (pUW235)	(1) Brewers' Mash (2) Distillers' Mash	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
23-8-00	A.02	Amino-peptidase	*Lactococcus lactis*	(1) Cheese (2) Dairy based flavouring preparations (3) Hydrolyzed animal, milk and vegetable protein	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice
	A.1	Amylase	*Aspergillus niger* var.; *Aspergillus oryzae* var.; *Bacillus subtilis* var.; *Rhizopus oryzae* var.; Barley Malt	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout (2) Bread; Flour; Whole wheat flour (3) Cider; Wine (4) Chocolate syrups (5) Distillers' Mash (6) Malt-flavoured dry breakfast cereals (7) Single-strength fruit juices (8) Precooked (instant) cereals (9) Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup) (10) Unstandardized bakery products	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice (6) Good Manufacturing Practice (7) Good Manufacturing Practice (8) Good Manufacturing Practice (9) Good Manufacturing Practice (10) Good Manufacturing Practice
18-1-90 27-4-78					
28-11-05			*Aspergillus niger* STz18-9 (pHUda7)	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout (2) Distillers' Mash (3) Starch used in the production of dextrins, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup), maltose	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice

TABLE V -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES -- (continued)

Item No.	Column I Additive	Column II Permitted Source	Column III Permitted in or upon	Column IV Maximum Level of Use
28-11-05	A.1 Amylase (cont'd)	*Bacillus amyloliquefaciens* EBA 20 (pUBH2); *Bacillus licheniformis; Bacillus licheniformis* BML 592 (pAmyAmp); *Bacillus licheniformis* BML 730 (pAmyAmp); *Bacillus licheniformis* LA 57 (pDN1981); *Bacillus licheniformis* LAT8 (pLAT3); *Bacillus licheniformis* LiH 1159 (pLiH1108); *Bacillus licheniformis* LiH 1464 (pLiH1346); *Bacillus licheniformis* PL 1303 (pPL1117)	(1) Distillers' Mash (2) Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup (3) Brewer's Mash	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice
11-10-84		*Bacillus stearothermophilus*	(1) Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup)	(1) Good Manufacturing Practice
27-8-92			(2) Distillers' Mash (3) Brewers' Mash (4) Bread; Flour; Whole wheat flour (5) Unstandardized bakery products	(2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice

TABLE V -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES -- (continued)

	Item No.	*Column I* *Additive*	*Column II* *Permitted Source*	*Column III* *Permitted in or Upon*	*Column IV* *Maximum Level of Use*
13-8-91	A.1	Amylase (cont'd)	*Bacillus subtilis* B1.109 (pCPC720) (ATCC 39705)	Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup)	Good Manufacturing Practice
30-4-92			*Bacillus subtilis* B1.109 (pCPC800)	(1) Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup)	(1) Good Manufacturing Practice
				(2) Distillers' Mash	(2) Good Manufacturing Practice
				(3) Brewers' Mash	(3) Good Manufacturing Practice
				(4) Bakery Products	(4) Good Manufacturing Practice
28-11-05	A.2	Amylase (malto-genic)	*Bacillus subtilis* DN1413 (pDN1413); *Bacillus subtilis* LFA 63 (pLFA63)	(1) Starch used in the production of dextrins, maltose, dextrose, glucose, (glucose syrup) or glucose solids (dried glucose syrup)	(1) Good Manufacturing Practice
13-1-94					
1-11-94				(2) Bread; Flour; Whole wheat flour	(2) Good Manufacturing Practice
				(3) Unstandardized bakery products	(3) Good Manufacturing Practice
26-6-80	B.1	Bovine Rennet	Aqueous extracts from the fourth stomach of adult bovine animals, sheep and goats	Cheese, cottage cheese, cream cheese, cream cheese with (named added ingredients), cream cheese spread, cream cheese spread with (named added ingredients)	Good Manufacturing Practice

	Item No.	*Column I* Additive	*Column II* Permitted Source	*Column III* Permitted in or Upon	*Column IV* Maximum Level of Use
	B.2	Bromelain	The pineapples *Ananas comosus* and *Ananas bracteatus*	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout	(1) Good Manufacturing Practice
				(2) Bread; Flour; Whole wheat flour	(2) Good Manufacturing Practice
12-11-81				(3) Sausage casings	(3) Good Manufacturing Practice
				(4) Hydrolyzed animal, milk and vegetable protein	(4) Good Manufacturing Practice
				(5) Meat cuts	(5) Good Manufacturing Practice
				(6) Meat tenderizing preparations	(6) Good Manufacturing Practice
				(7) Pumping pickle for the curing of beef cuts	(7) Good Manufacturing Practice in accordance with paragraph B.14.009(g)
				(8) Sugar wafers, waffles, pancakes	(8) Good Manufacturing Practice
27-4-78	C.1	Catalase	*Aspergillus niger* var.; *Micrococcus lysodeikticus*; Bovine (*Bos taurus*) liver	(1) Soft drinks	(1) Good Manufacturing Practice
13-9-79				(2) Egg albumen	(2) Good Manufacturing Practice
2-12-82				(3) Liquid whey treated with hydrogen peroxide in accordance with item H.1, Table VIII	(3) Good Manufacturing Practice
	C.2	Cellulase	*Aspergillus niger* var.	(1) Distillers' Mash	(1) Good Manufacturing Practice
				(2) Liquid coffee concentrate	(2) Good Manufacturing Practice
				(3) Spice extracts; Natural flavour and colour extractives	(3) Good Manufacturing Practice
18-1-90			*Trichoderma reesei* QM 9414	(1) Single-strength fruit juices	(1) Good Manufacturing Practice
20-11-97				(2) Tea leaves for the production of tea solids	(2) Good Manufacturing Practice

*(R) Minor correction

TABLE V -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES -- (continued)

Item No.	Column I Additive	Column II Permitted Source	Column III Permitted in or Upon	Column IV Maximum Level of Use
C.3	Chymosin (i) Chymosin A	*Escherichia coli* K-12, GE81 (pPFZ87A)	(1) Cheddar cheese; (naming the variety) cheese; Cottage cheese; Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Sour cream	(1) Good Manufacturing Practice
7-11-95			(2) Unstandardized milk-based dessert preparations	(2) Good Manufacturing Practice
	(ii) Chymosin B	*Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR); *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105)	(1) Cheddar cheese; (naming the variety) cheese; Cottage cheese; Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Sour cream	(1) Good Manufacturing Practice
7-11-95			(2) Unstandardized milk-based dessert preparations	(2) Good Manufacturing Practice
F.1	Ficin	Latex of fig tree (*Ficus* sp.)	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout	(1) Good Manufacturing Practice
			(2) Sausage casings	(2) Good Manufacturing Practice
			(3) Hydrolyzed animal, milk and vegetable protein	(3) Good Manufacturing Practice
12-11-81			(4) Meat cuts	(4) Good Manufacturing Practice
			(5) Meat tenderizing preparations	(5) Good Manufacturing Practice
			(6) Pumping pickle for the curing of beef cuts	(6) Good Manufacturing Practice in accordance with paragraph B.14.009(g)

*(R) Minor correction

Item No.	Column I Additive	Column II Permitted Source	Column III Permitted in or upon	Column IV Maximum Level of Use
	G.1 Glucoamylase (Amyloglucosidase; Maltase)	*Aspergillus niger* var; *Aspergillus oryzae* var.; *Rhizopus oryzae* var.	(1) Ale; Beer; Light beer; Malt liquor; Porter Stout	(1) Good Manufacturing Practice
27-4-78			(2) Bread; Flour; Whole wheat flour	(2) Good Manufacturing Practice
			(3) Chocolate syrups	(3) Good Manufacturing Practice
			(4) Distillers' Mash	(4) Good Manufacturing Practice
			(5) Precooked (instant) cereals	(5) Good Manufacturing Practice
26-6-80			(6) Starch used in the preparation of dextrins, maltose, dextrose, glucose (glucose syrup), or glucose solids (dried glucose syrups)	(6) Good Manufacturing Practice
			(7) Unstandardized bakery products	(7) Good Manufacturing Practice
28-11-05		*Aspergillus niger* STz18-9 (pHUda7)	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout	(1) Good Manufacturing Practice
			(2) Distillers' Mash	(2) Good Manufacturing Practice
			(3) Starch used in the production of dextrins, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup), maltose	(3) Good Manufacturing Practice
		Rhizopus niveus var.	(1) Distillers' Mash	(1) Good Manufacturing Practice
			(2) Mash destined for vinegar manufacture	(2) Good Manufacturing Practice
		Rhizopus delemar var.; *Multiplici sporus*	(1) Brewers' Mash	(1) Good Manufacturing Practice
			(2) Distillers' Mash	(2) Good Manufacturing Practice
			(3) Mash destined for vinegar manufacture	(3) Good Manufacturing Practice
			(4) Starch used in the production of dextrins, maltose, dextrose, glucose, (glucose syrup), or glucose solids (dried glucose syrup)	(4) Good Manufacturing Practice

TABLE V -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES -- (continued)

	Item No.	*Column I* *Additive*	*Column II* *Permitted Source*	*Column III* *Permitted in or Upon*	*Column IV* *Maximum Level of Use*
	G.2	Glucanase	*Aspergillus niger* var.; *Bacillus Subtilis* var.	(1) Ale; Beer; Light beer; Malt Liquor; Porter; Stout	(1) Good Manufacturing Practice
				(2) Corn for degermation	(2) Good Manufacturing Practice
				(3) Distillers' Mash	(3) Good Manufacturing Practice
				(4) Mash destined for vinegar manufacture	(4) Good Manufacturing Practice
				(5) Unstandardized bakery products	(5) Good Manufacturing Practice
20-11-97			*Humicola insolens* var.	(1) Ale; Beer, Light beer, Malt liquor; Porter; Stout	(1) Good Manufacturing Practice
				(2) Distillers' Mash	(2) Good Manufacturing Practice
27-4-78 13-9-79	G.3	Glucose oxidase	*Aspergillus niger* var.	(1) Soft drinks	(1) Good Manufacturing Practice
				(2) Liquid whole egg; Egg white (albumen); and Liquid egg yolk destined for drying	(2) Good Manufacturing Practice in accordance with paragraphs B.22.034(b), B.22.035(b) and B.22.036(b)
5-4-05 18-2-97				(3) Bread; Flour; Whole wheat flour	(3) Good Manufacturing Practice
				(4) Unstandardized bakery products	(4) Good Manufacturing Practice
28-11-05 13-9-79 26-6-80 12-5-88 2-4-92	G.4	Glucose Isomerase	*Bacillus coagulans* var.; *Streptomyces olivochromogenes* var.; *Actinoplanes missouriensis* var.; *Streptomyces olivaceus* var.; *Microbacterium arborescens* NRRL B-11022; *Streptomyces murinus* DSM 3252; *Streptomyces rubiginosus* ATCC No. 21,175; *Streptomyces ribuginosus* SYC 5406 (pSYC5239)	(1) Glucose (glucose syrup) to be partially or completely isomerized to fructose	(1) Good Manufacturing Practice
	H.1	Hemi-cellulase	*Bacillus subtilis* var.	(1) Distillers' Mash	(1) Good Manufacturing Practice
				(2) Liquid coffee concentrate	(2) Good Manufacturing Practice
				(3) Mash destined for vinegar manufacture	(3) Good Manufacturing Practice

TABLE V -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES -- (continued)

	Item No.	*Column I* Additive	*Column II* Permitted Source	*Column III* Permitted in or Upon	*Column IV* Maximum Level of Use
7-1-97	I.01	Inulinase	*Aspergillus niger var. Tieghem*	Inulin	Good Manufacturing Practice
	I.1	Invertase	*Saccharomyces* sp.	(1) Soft-centred and liquid-centred confections (2) Unstandardized bakery foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
5-4-05 10-1-86 1-4-82 12-9-84	L.1	Lactase	*Aspergillus niger* var.; *Aspergillus oryzae* var.; *Kluyveromyces fragilis* (*Kluyveromyces marxianus* var. *marxianus*); *Kluyveromyces lactis* (*Kluyveromyces marxianus* var. *lactis*); *Saccharomyces* sp.	(1) Lactose-reducing enzyme preparations (2) Milk destined for use in ice cream mix (3) Bread; Flour, Whole wheat flour (4) (naming the flavour) milk; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) malted milk; (naming the flavour) skimmed milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice
			Cell-free extracts from *Candida pseudotropicalis*	(1) Milk destined for use in ice cream mix (2) Yogurt (3) Whey (4) (naming the flavour) milk; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) malted milk; (naming the flavour) skimmed milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice

TABLE V -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES -- (continued)

	Item No.	*Column I* *Additive*	*Column II* *Permitted Source*	*Column III* *Permitted in or Upon*	*Column IV* *Maximum Level of Use*
5-4-05	L.2	Lipase	Animal pancreatic tissue; *Aspergillus niger* var.;	(1) Dairy based flavouring preparations	(1) Good Manufacturing Practice
9-12-97			*Aspergillus oryzae* var.; Edible forestomach tissue of calves, kids or lambs; *Rhizopus oryzae* var.	(2) Liquid and dried egg white (liquid and dried albumen)	(2) Good Manufacturing Practice
27-4-78				(3) Asiago cheese; blue cheese; Caciocavallo cheese; Cheddar cheese; Cheddar cheese for processing (Cheddar cheese; stirred curd cheese; granular curd cheese; washed curd cheese); Feta cheese; Parmesan cheese; Provolone cheese; Romano cheese	(3) Good Manufacturing Practice
12-9-84					
3-6-82					
9-12-97					
5-4-05				(4) Bread; Flour; Whole wheat flour	(4) Good Manufacturing Practice
23-8-00				(5) Unstandardized bakery products	(5) Good Manufacturing Practice
				(6) Hydrolyzed animal, milk and vegetable protein	(6) Good Manufacturing Practice
5-4-05			*Aspergillus oryzae* (MLT-2) (pRML 787) (p3SR2); *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei (Cooney and Emerson)*); *Rhizopus niveus*	(1) Modified fats and oils	(1) Good Manufacturing Practice
7-11-95				(2) Cheese	(2) Good Manufacturing Practice
23-8-00				(3) Dairy based flavouring preparations	(3) Good Manufacturing Practice
				(4) Hydrolyzed animal, milk and vegetable protein	(4) Good Manufacturing Practice
7-10-96			*Penicillium camembertii*	(1) Edible fats and oils	(1) Good Manufacturing Practice
1-11-94	L.3	Lipoxidase	Soyabean whey or meal	(1) Bread; Flour; Whole wheat flour	(1) Good Manufacturing Practice
30-11-00	L.4	Lysozyme	Egg white	Cheese	Good Manufacturing Practice

TABLE V -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES -- (continued)

Item No.	Column I Additive	Column II Permitted Source	Column III Permitted in or Upon	Column IV Maximum Level of Use
5-4-05 8-1-81 15-9-98 12-4-84 2-6-94	M.1	Milk coagulating enzyme	*Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)) or *Mucor pusillus Lindt* by pure culture fermentation process or *Aspergillus oryzae* RET-1 (pBoel777) *Endothia parasitica* by pure culture fermentation processes	(1) Cheese, Cottage cheese; Sour cream	(1) Good Manufacturing Practice
	P.1	Pancreatin	Pancreas of the hog (*Sus scrofa*) or ox (*Bos taurus*)	(1) Liquid and dried egg white (liquid and dried albumen)	(1) Good Manufacturing Practice
13-9-79				(2) Precooked (instant) cereals	(2) Good Manufacturing Practice
				(3) Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup), or glucose solids (dried glucose syrup)	(3) Good Manufacturing Practice
14-12-89				(4) Hydrolyzed animal, milk and vegetable proteins	(4) Good Manufacturing Practice
	P.2	Papain	Fruit of the papaya *Carica papaya L.* (*Fam. Caricaceae*)	(1) Ale; Beer; Light beer; Malt Liquor; Porter; Stout	(1) Good Manufacturing Practice
12-11-81				(2) Beef before slaughter	(2) Good Manufacturing Practice
				(3) Sausage casings; Water soluble edible collagen films	(3) Good Manufacturing Practice
				(4) Hydrolyzed animal, milk and vegetable protein	(4) Good Manufacturing Practice
				(5) Meat cuts	(5) Good Manufacturing Practice
				(6) Meat tenderizing preparations	(6) Good Manufacturing Practice
27-4-78				(7) Precooked (instant) cereals	(7) Good Manufacturing Practice
				(8) Pumping pickle for the curing of beef cuts	(8) Good Manufacturing Practice
30-4-87				(9) Unstandardized bakery products	(9) Good Manufacturing Practice

TABLE V -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES -- (continued)

Item No.	Column I Additive	Column II Permitted Source	Column III Permitted in or Upon	Column IV Maximum Level of Use
	P.3	Pectinase	*Aspergillus niger* var.; *Rhizopus oryzae* var.	(1) Cider; Wine	(1) Good Manufacturing Practice
				(2) Distillers' Mash	(2) Good Manufacturing Practice
18-1-90				(3) Single-strength fruit juices	(3) Good Manufacturing Practice
				(4) Natural flavour and colour extractives	(4) Good Manufacturing Practice
				(5) Skins of citrus fruits destined for jam, marmalade and candied fruit production	(5) Good Manufacturing Practice
				(6) Vegetable stock for use in soups	(6) Good Manufacturing Practice
20-11-97				(7) Tea leaves for the production of tea solids	(7) Good Manufacturing Practice
13-9-06			*Aspergillus oryzae*	(1) Cider; Wine	(1) Good Manufacturing Practice
28-11-05			Km-1-1 (pA2PEI)	(2) Single-strength fruit juices	(2) Good Manufacturing Practice
				(3) Unstandardized fruit and vegetable products	(3) Good Manufacturing Practice
	P.4	Pentosanase	*Aspergillus niger* var.; *Bacillus subtilis* var.	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout	(1) Good Manufacturing Practice
				(2) Corn for degermination	(2) Good Manufacturing Practice
				(3) Distillers' Mash	(3) Good Manufacturing Practice
				(4) Mash destined for vinegar manufacture	(4) Good Manufacturing Practice
				(5) Unstandardized bakery products	(5) Good Manufacturing Practice
11-1-95				(6) Bread; Flour; Whole wheat flour	(6) Good Manufacturing Practice
			Trichoderma reesei (QM9414)	(1) Bread; Flour; Whole wheat flour	(1) Good Manufacturing Practice
23-1-92				(2) Distillers' Mash	(2) Good Manufacturing Practice
				(3) Unstandardized bakery products	(3) Good Manufacturing Practice

Item No.	Column I Additive	Column II Permitted Source	Column III Permitted in or Upon	Column IV Maximum Level of Use
P.5	Pepsin	Glandular layer of porcine stomach	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout	(1) Good Manufacturing Practice
			(2) Cheese; Cottage cheese; Cream Cheese; Cream cheese with (added named ingredients); Cream cheese spread; Cream cheese spread with (added named ingredients)	(2) Good Manufacturing Practice
			(3) Defatted soya flour	(3) Good Manufacturing Practice
			(4) Precooked (instant) cereals	(4) Good Manufacturing Practice
			(5) Hydrolyzed animal, milk and vegetable proteins	(5) Good Manufacturing Practice
P.6	Protease	*Aspergillus oryzae* var.; *Aspergillus niger* var.; *Bacillus subtilis* var.	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout	(1) Good Manufacturing Practice
			(2) Bread; Flour; Whole wheat flour	(2) Good Manufacturing Practice
			(3) Dairy based flavouring preparations	(3) Good Manufacturing Practice
			(4) Distillers' Mash	(4) Good Manufacturing Practice
			(5) Sausage casings	(5) Good Manufacturing Practice
			(6) Hydrolyzed animal, milk and vegetable protein	(6) Good Manufacturing Practice
			(7) Industrial spray-dried cheese powder	(7) Good Manufacturing Practice
			(8) Meat cuts	(8) Good Manufacturing Practice
			(9) Meat tenderizing preparations	(9) Good Manufacturing Practice
			(10) Precooked (instant) cereals	(10) Good Manufacturing Practice
			(11) Unstandardized bakery foods	(11) Good Manufacturing Practice
			(12) Cheddar cheese; Cheddar cheese for processing (granular curd cheese; Stirred curd cheese; Washed curd cheese); Colby cheese	(12) Good Manufacturing Practice

27-4-78
14-12-89
10-1-86
27-7-90
1-11-94

TABLE V -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES -- (continued)

Item No.	Column I Additive	Column II Permitted Source	Column III Permitted in or Upon	Column IV Maximum Level of Use
P.6	Protease (cont'd)	*Micrococcus caseolyticus* var.	(1) Hard or semi-hard, pressed and soft varietal cheeses	(1) Good Manufacturing Practice
16-2-94		*Bacillus licheniformis* (Cx)	(1) Hydrolyzed animal, milk and vegetable protein	(1) Good Manufacturing Practice
28-11-05 P.7	Pullulanase	*Bacillus acido-pullulyticus* NCIB 11647; *Bacillus licheniformis* SE2-Pul-int211 (pUBCDEBRA11 DNSI)	(1) Bread; Flour; Whole wheat flour (2) Starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or fructose syrups and solids, maltose (3) Unstandardized bakery products	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice
		Bacillus licheniformis BMP 139 (pR11Amp)	(1) Bread; Flour; Whole wheat flour (2) Brewers' Mash (3) Starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or fructose syrups and solids, maltose (4) Unstandardized bakery products	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice
		Bacillus subtilis B1-163 (pEB301)	(1) Bread; Flour; Whole wheat flour (2) Brewers' Mash (3) Distillers' Mash (4) Starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or fructose syrups and solids, maltose (5) Unstandardized bakery products	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice

Item No.	Column I Additive	Column II Permitted source	Column III Permitted in or upon	Column IV Maximum Level of Use
27-4-78	R.1 Rennet	Aqueous extracts from fourth stomach of calves, kids, or lambs	(1) Cheese; Cottage cheese; Cream cheese; Cream cheese with (added named ingredients); Cream cheese spread; Cream cheese spread with (added named ingredients); sour cream	(1) Good Manufacturing Practice
16-11-78			(2) Unstandardized milk based dessert preparations	(2) Good Manufacturing Practice

	Item No.	*Column I* Additive	*Column II* Permitted Source	*Column III* Permitted in or Upon	*Column IV* Maximum Level of Use
22-4-04	T.01	Transglut-aminase	*Streptoverticillium mobaraense* strain S-8112	(1) Prepared fish products (except for any of these products for which standards are set out in these Regulations)	(1) Good Manufacturing Practice
				(2) Simulated meat products	(2) Good Manufacturing Practice
				(3) Cheese products (except for any of these products for which standards are set out in these Regulations)	(3) Good Manufacturing Practice
				(4) Processed cheese products (except for any of these products for which standards are set out in these Regulations)	(4) Good Manufacturing Practice
				(5) Cream cheese products (except for any of these products for which standards are set out in these Regulations)	(5) Good Manufacturing Practice
				(6) Yogurt	(6) Good Manufacturing Practice
				(7) Frozen dairy desserts (except for any of these products for which standards are set out in these Regulations)	(7) Good Manufacturing Practice
14-12-89	T.1	Trypsin	Pancreas of the hog (*Sus scrofa*)	(1) Hydrolyzed animal, milk and vegetable proteins	(1) Good Manufacturing Practice
3-4-03	X.1	Xylanase	*Aspergillus oryzae* Fa 1-1 (pA2X1T1)	Bread; Flour; Whole wheat flour	Good Manufacturing Practice

TABLE VI
FOOD ADDITIVES THAT MAY BE USED AS FIRMING AGENTS

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
A.1	Aluminum Sulphate	(1) Canned crabmeat, lobster, salmon, shrimp and tuna; Pickles and relishes	(1) Good Manufacturing Practice
		(2) Unstandardized foods	(2) Good Manufacturing Practice
A.2	Ammonium Aluminum Sulphate	(1) Pickles and relishes	(1) Good Manufacturing Practice
		(2) Unstandardized foods	(2) Good Manufacturing Practice
C.1 14-7-66	Calcium Chloride	(1) Canned apples	(1) 0.026% calculated as calcium
		(2) Canned grapefruit	(2) 0.035% calculated as calcium in accordance with subparagraph B.11.101(c)(vii)
		(3) (named variety) cheese; Cheddar cheese	(3) 0.02% of the milk and milk products used
		(4) Cottage cheese	(4) Good Manufacturing Practice
		(5) Glaze of frozen fish	(5) Good Manufacturing Practice
26-8-93		(6) Olives	(6) 1.5% of the brine
		(7) Pickles and relishes	(7) 0.4%
18-10-79		(8) Tomatoes; Canned vegetables (naming the vegetable); Frozen apples	(8) 0.026% calculated as calcium, and in the case of canned peas 0.035% calculated as calcium
		(9) Unstandardized foods	(9) Good Manufacturing Practice
C.2	Calcium Citrate	(1) Tomatoes; Canned vegetables; Frozen apples; Frozen sliced apples	(1) 0.026% calculated as calcium
17-11-77		(2) Canned apples	(2) 0.026% calculated as calcium
		(3) Unstandardized foods	(3) Good Manufacturing Practice
C.3	Calcium Gluconate	Unstandardized foods	Good Manufacturing Practice
C.3A 17-11-77	Calcium Lactate	(1) Canned grapefruit	(1) 0.035% calculated as calcium in accordance with subparagraph B.11.101(c)(vii)
13-9-79		(2) Canned peas	(2) 0.035% calculated as calcium
C.4	Calcium Phosphate, dibasic	Unstandardized foods	Good Manufacturing Practice
C.5	Calcium Phosphate, monobasic	(1) Tomatoes; Canned vegetables; Frozen apples	(1) 0.026% calculated as calcium
17-11-77		(2) Canned apples	(2) 0.026% calculated as calcium
		(3) Unstandardized foods	(3) Good Manufacturing Practice

*(R) Minor correction

TABLE VI -- (concluded)
FOOD ADDITIVES THAT MAY BE USED AS FIRMING AGENTS

Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
C.6	Calcium Sulphate	(1) Tomatoes; Canned vegetables; Frozen apples (2) Canned apples	(1) 0.026% calculated as calcium (2) 0.026% calculated as calcium
P.1	Potassium Aluminum Sulphate	(1) Pickles and relishes (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
S.1	Sodium Aluminum Sulphate	(1) Pickles and relishes (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice

17-11-77

TABLE VII
FOOD ADDITIVES THAT MAY BE USED AS GLAZING AND POLISHING AGENTS

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
31-1-66	A.1	Acetylated Mono-glycerides	(1) Confectionery (2) Frozen fish	(1) 0.4% (2) Good Manufacturing Practice
	B.1	Beeswax	Confectionery	0.4%
	C.1	Carnauba Wax	Confectionery	0.4%
25-3-65	C.2	Candelilla Wax	Confectionery	0.4%
	G.1	Gum Arabic	Confectionery	0.4%
25-3-65	G.2	Gum Benzoin	Confectionery	0.4%
	M.1	Magnesium Silicate	Confectionery	0.4%
	M.2	Mineral Oil	Confectionery	0.15%
	P.1	Petrolatum	Confectionery	0.15%
	S.1	Shellac	Cake decorations; Confectionery	0.4%
	S.2	Spermaceti Wax	Confectionery	0.4%
	Z.1	Zein	Confectionery	1.0%

*(R) Minor correction

TABLE VIII
MISCELLANEOUS FOOD ADDITIVES

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
11-5-06	A.01	Acacia Gum	Ale; Beer; Light beer; Malt liquor; Porter; Stout; Wine	Fining agent	Good Manufacturing Practice
	A.1	Acetylated Mono-glycerides	Unstandardized foods	Coating: Release agent	Good Manufacturing Practice
11-5-06	A.1.01	Agar	Wine	Fining Agent	Good Manufacturing Practice
28-4-77	A.1.1	Aluminum Sulphate	Liquid or frozen whole egg; Egg white (albumen) or egg yolk	To stabilize albumen during pasteurization	0.036%
10-12-74	A.2	Ammonium Persulphate	Brewer's yeast	Antimicrobial agent	0.1%
25-5-93	A.3	Revoked by P.C. 1993-1038 of May 25, 1993.			

TABLE VIII -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
25-5-93	A.4	Revoked by P.C. 1993-1038 of May 25, 1993.			
	B.2	Beeswax	Unstandardized foods	Antisticking agent	0.4%
23-11-89	B.2.1	Benzoyl Peroxide	Liquid whey destined for the manufacture of dried whey products other than those for use in infant formula	To decolourize	100 p.p.m.
16-6-70 28-4-77	B.3	Brominated vegetable oil	(naming the flavour) Flavour for use in citrus-flavoured or spruce-flavoured beverages	Density adjusting agent	15 p.p.m. in citrus-flavoured or spruce-flavoured beverages as consumed
27-4-78	B.4	n-Butane	Edible vegetable oil-based or lecithin-based pan coatings or a mixture of both	Propellant	Good Manufacturing Practice
	C.1	Caffeine	Cola type beverages	To characterize the product	200 p.p.m. in the finished product
	C.2	Caffeine Citrate	Cola type beverages	To characterize the product	200 p.p.m. calculated as caffeine, in the finished product

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
	C.3	Calcium Carbonate	(1) Flour; Whole wheat flour	(1) Carrier of benzoyl peroxide	(1) 900 p.p.m. in accordance with subparagraphs B.13.001(e)(vi) and B.13.005(d)(vi)
1-3-94 31-7-80 15-6-67			(2) Confectionery	(2) Creaming and fixing agent	(2) Good Manufacturing Practice
			(3) Chewing gum	(3) Filler	(3) Good Manufacturing Practice
			(4) Unstandardized food	(4) Carrier and dusting agent	(4) Good Manufacturing Practice
	C.3A	Calcium Lactate	(1) Egg albumen (delysozymized)	(1) Restoration of functional properties	(1) Good Manufacturing Practice (Quantity of calcium added not to exceed that lost during processing)
7-7-83 4-6-92			(2) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(2) To modify texture	(2) Good Manufacturing Practice
6-4-89	C.4	Calcium Oxide	(1) Frozen crustaceans and molluscs	(1) To facilitate the removal of extraneous matter and to reduce moisture loss during cooking	(1) When used in combination with sodium chloride (salt) and sodium hydroxide in solution, calcium oxide not to exceed 30 p.p.m.
4-6-92			(2) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(2) To modify texture	(2) Good Manufacturing Practice

*(R) Minor correction

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
15-6-67 1-3-94 31-7-80	C.5	Calcium Phosphate dibasic	(1) Flour; Whole wheat flour	(1) Carrier of benzoyl peroxide	(1) 900 p.p.m. in accordance with subparagraphs B.13.001(e)(vi) and B.13.005(d)(vi)
1-3-94 31-7-80	C.6	Calcium Phosphate tribasic	(1) Flour; Whole wheat flour	(1) Carrier of benzoyl peroxide	(1) 900 p.p.m. in accordance with subparagraphs B.13.001(e)(vi) and B.13.005(d)(vi)
23-11-89			(2) Liquid whey destined for the manufacture of dried whey products other than those for use in infant formula	(2) Carrier of benzoyl peroxide	(2) 0.04% of dried whey product
13-6-91			(3) Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients)	(3) To improve colour, texture, consistency and spreadability	(3) 1.0%
	C.7	Calcium Silicate	Oil-soluble annatto	Carrier	Good Manufacturing Practice
	C.8	Calcium Stearate	Confectionery	Release agent	Good Manufacturing Practice

*(R) Minor correction

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Purpose of Use	*Column IV* Maximum Level of Use
8-10-69	C.9	Calcium Stearoyl-2-Lactylate	(1) Liquid and frozen egg whites	(1) Whipping agent	(1) 0.05%
17-12-69			(2) Dried egg whites	(2) Whipping agent	(2) 0.5%
23-1-74			(3) Vegetable fat toppings	(3) Whipping agent	(3) 0.3%
			(4) Dehydrated potatoes	(4) Conditioning agent	(4) 0.2% of dry weight
1-3-94	C.10	Calcium Sulphate	(1) Flour; Whole wheat flour	(1) Carrier of benzoyl peroxide	(1) 900 p.p.m in accordance with subparagraphs B.13.001(e)(vi) and B.13.005(d)(vi)
31-7-80			(2) Baking powder	(2) Neutral filler	(2) Good Manufacturing Practice
25-8-76	C.11	Carbon Dioxide	(1) Ale; Beer; Carbonated (naming the fruit) juice; Cider; Light beer; Malt liquor; Porter; Stout; Wines; Water represented as mineral water or spring water	(1) Carbonation	(1) Good Manufacturing Practice
			(2) Unstandardized foods	(2) Carbonation and pressure dispensing agent	(2) Good Manufacturing Practice
1-3-01			(3) Cottage Cheese; Creamed Cottage Cheese	(3) To extend durable life	(3) Good Manufacturing Practice
	C.12	Castor Oil	Confectionery	Release agent	Good Manufacturing Practice
1-10-68	C.13	Cellulose, Microcrystalline	(1) Ice milk mix	(1) Bodying and texturizing agent	(1) 1.5%
			(2) Sherbet	(2) Bodying and texturizing agent	(2) 0.5%
			(3) Carbohydrate or calorie reduced dietetic foods	(3) Filler	(3) Good Manufacturing Practice
25-2-69			(4) Whipped vegetable oil topping	(4) Bodying and texturizing agent	(4) 1.5%
			(5) Unstandardized frozen desserts	(5) Bodying and texturizing agent	(5) 0.5%

*(R) Minor correction

	Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Purpose of Use*	*Column IV* *Maximum Level of Use*
	C.13	Cellulose, Micro-crystalline (conc.)	(6) Unstandardized sandwich spreads and dips	(6) Bodying and texturizing agent	(6) 3.0%
27-3-73			(7) Unstandardized foods other than those unstandardized foods in this item	(7) Bodying and texturizing agent	(7) 2.0%
23-1-74			(8) Ice cream mix	(8) Bodying and texturizing agent	(8) 0.5% or, if used in combination with stabilizing agents, the combined amount shall not exceed 0.5% of the ice cream made from the mix
18-12-75					
5-5-83			(9) Table-top sweetener tablets containing aspartame	(9) Tablets dis-integration	(9) 2.2%
11-8-88			(10) Cream for whipping, heat-treated above 100°C	(10) Stabilizing and thickening agent	(10) 0.2%
31-1-66	C.14A	Chloropenta-fluoroethane	Unstandardized foods	Pressure dispensing and aerating agent	Good Manufacturing Practice
	C.15	Citric Acid	(1) Beef blood	(1) Anticoagulant	(1) Good Manufacturing Practice
			(2) Unstandardized foods	(2) Culture nutrient	(2) Good Manufacturing Practice
23-1-74	C.16	Copper gluconate	Breath freshener products in candy, tablet or gum form	To characterize the product	50 p.p.m.
11-5-06	C.17	Copper Sulphate	Wine	Fining agent	0.0001 %, calculated as copper, in the finished product

TABLE VIII -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
D.1	Dimethylpoly-siloxane Formulations	(1) Apple or (rhubarb) and (naming the fruit) Jam; Fats and oils; Fig marmalade; Fig marmalade with pectin; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Pineapple marmalade with pectin; Reconstituted lemon juice ; Reconstituted lime juice; Shortening; Skim milk powder; Wine	(1) Antifoaming agent	(1) 10 p.p.m. of dimethylpolysiloxane
3-2-77				
31-12-90		(2) Pineapple juice: Blends of pineapple juice with other fruit juices; canned pineapple (when pineapple juice is used as the packing medium)	(2) Antifoaming agent	(2) 10 p.p.m of dimethylpolysiloxane
17-11-77				
3-6-82		(3) Surfaces that come in contact with food	(3) Release agent	(3) Good Manufacturing Practice (Residue of dimethylpolysiloxane in food not to exceed 10 p.p.m.)
		(4) Unstandardized foods	(4) Antifoaming agent	(4) 10 p.p.m. of dimethylpolysiloxane
		(5) Wort used in the manufacture of Ale, Beer, Light beer; Malt liquor, Porter and Stout	(5) Antifoaming agent	(5) 10 p.p.m. of dimethylpolysiloxane

*(R) Minor correction

TABLE VIII -- (continued)

	Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Purpose of Use*	*Column IV* *Maximum Level of Use*
31-1-66 7-10-96	D.3	Dioctyl sodium sulfo-succinate	(1) Fumaric acid-acidulated dry beverage bases (2) Sausage casings	(1) Wetting agent (2) Reduce casing breakage	(1) 10 p.p.m. in the finished drink (2) 200 p.p.m. of the casing
22-1-81	E.1	Ethoxyquin	Paprika; Ground Chili Pepper	To promote colour retention	100 p.p.m
22-1-81	E.2	Ethylene oxide	Whole or ground spice (except mixtures containing salt)	Fumigation	G.M.P. (Residues of ethylene chlorohydrin not to exceed 1,500 p.p.m.)
	F.1	Ferrous Gluconate	Ripe olives	Colour retention	Good Manufacturing Practice
11-5-06	G.1	Gelatin	Beer; Cider; Wine	Fining agent	Good Manufacturing Practice
23-3-89	G.2	Revoked by P.C. 1989-475 of March 23, 1989			
14-1-70	G.2A	Glucono delta lactone	(1) Cooked sausage, Meat loaf (2) Dry sausage	(1) To accelerate colour fixing (2) To assist in curing	(1) 0.5% (2) Good Manufacturing Practice
	G.3	Glycerol	(1) Meat curing compounds; Sausage casings (2) Preserved meats (Division 14) (3) Unstandardized foods	(1) Humectant (2) Glaze for pre-served meats (3) Humectant; Plasticizer	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice
11-2-99	G.4	Glycerol ester of wood rosin	Citrus-flavoured or spruce-flavoured beverages	Density adjusting agent	100 p.p.m.
2-12-82	H.1	Hydrogen Peroxide	(1) Brewers' Mash (2) Liquid whey destined for the manufacture of dried whey products	(1) Clarification aid (2) To decolourize and maintain pH	(1) 135 p.p.m. in the mash (2) 100 p.p.m. (see also sub-item C.1(3) of Table V)

TABLE VIII -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
18-12-75	I.	Isobutane	Edible vegetable oil-based or lecithin-based pan coatings or a mixture of both	Propellant	Good Manufacturing Practice
25-3-65	L.1	Lactylic Esters of Fatty Acids	Unstandardized foods	Plasticizing Agent	Good Manufacturing Practice
	L.2	Lanolin	Chewing Gum	Plasticizing Agent	Good Manufacturing Practice
28-4-77	L.3	Lecithin	Surfaces that come in contact with food	Release Agent	Good Manufacturing Practice
23-7-81	L.4	L-Leucine	Table-top sweetener tablets containing aspartame	Lubricant in tablet manufacture	3% of tablet weight
	M.1	Magnesium Aluminium Silicate	Chewing Gum	Dusting agent	Good Manufacturing Practice
1-3-94 15-6-67 31-7-80	M.2	Magnesium Carbonate	(1) Flour, Whole wheat flour (2) Confectionery	(1) Carrier of benzoyl peroxide (2) Release agent	(1) 900 p.p.m in accordance with subparagraphs B.13.001(e)(vi) and B.13.005(d)(vi) (2) Good Manufacturing Practice
7-7-83	M.2A	Magnesium Chloride	Egg albumen (delysozymized)	Restoration of functional properties	Good Manufacturing Practice (Quantity of magnesium added not to exceed that lost during processing)
	M.3	Magnesium Silicate	(1) Confectionery (2) Chewing Gum (3) Rice	(1) Release agent (2) Dusting agent (3) Coating	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice
23-1-74	M.4	Magnesium Stearate	(1) Confectionery (2) Foods sold in tablet form	(1) Release agent (2) Binding agent	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
7-7-83	M.4A	Magnesium Sulphate	Egg albumen (delysozymized)	Restoration of functional properties	Good Manufacturing Practice (Quantity of magnesium added not to exceed that lost during processing)

*(R) Minor correction

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
25-5-93	M.5A	Revoked by P.C. 1993-1038 of May 25, 1993.			
	M.5C	Methyl Ethyl Cellulose	Unstandardized Foods	Aerating agent	Good Manufacturing Practice
	M.6	Micro-crystalline Cellulose	Same foods as listed for Cellulose, Microcrystalline	Filler	Same levels as prescribed for Cellulose Microcrystalline
2-12-82	M.7	Mineral Oil	(1) Bakery products; Confectionery; Seeded raisins	(1) Release agent	(1) 0.3% in accordance with section B.01.047. If petrolatum is also used as a release agent in bakery products the total of any combination of Petrolatum and mineral oil must not exceed 0.15%
			(2) Fresh fruits and vegetables	(2) Coating	(2) 0.3% in accordance with Section B.01.047
12-11-81			(3) Sausage casings	(3) Lubricant	(3) 5% in accordance with paragraph B.01.047(e) (Residues of mineral oil in raw sausage prepared with such casings not to exceed 200 p.p.m.; in cooked sausage, 30 p.p.m.)
15-12-83			(4) Salt substitute	(4) Binding agent and protective coating	(4) 0.6% in accordance with paragraph B.01.047(h)
	M.8	Monoacetin	Unstandardized bakery foods	Plasticizer	Good Manufacturing Practice
	M.9	Mono-and di-glycerides	(1) Apple (or rhubarb) and (naming the fruit) Jam; Fats and Oils; Fig marmalade; with pectin; (naming the fruit) Jam; (naming the fruit) Jam with pectin; naming the fruit)	(1) Antifoaming agent	(1) Good Manufacturing Practice

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
M.9	Mono and di-glycerides (Conc.)	Jelly; (naming the fruit) Jelly with pectin; (Naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Pineapple marmalade; Pineapple marmalade with pectin (2) Unstandardized foods	(2) Antifoaming agent; Humectant; Release agent	(2) Good Manufacturing Practice
M.10 23-1-75	Mono-glycerides	Unstandardized foods	Antifoaming agent; Humectant; Release agent	Good Manufacturing Practice
N.1 18-10-79	Nitrogen	(1) Cream cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients) (2) Margarine (3) Unstandardized foods	(1) To improve spreadability (2) To improve spreadability (3) Pressure dispensing agent	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice
N.2	Nitrous Oxide	Unstandardized foods	Pressure dispensing agent	Good Manufacturing Practice
O.1	Octafluoro-cycloubutane	Unstandardized foods	Pressure dispensing and aerating agent	Good Manufacturing Practice
O.2 12-1-71	Oxystearin	Cotton seed oil; Peanut oil; Soy bean oil	To inhibit crystal formation	0.125%
O.3 25-8-76	Ozone	(1) Cider (2) Water represented as mineral water or spring water (3) Wine	(1) Maturing agent (2) Chemosterilant (3) Maturing agent	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice

*(R) Minor correction

TABLE VIII -- (continued)

	Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Purpose of Use*	*Column IV* *Maximum Level of Use*
31-1-66	P.1	Pancreas Extract	Acid producing bacterial cultures	To control bacterio-phages	Good Manufacturing Practice
31-1-66	P.1A	Paraffin Wax	(1) Fresh fruits and vegetables (2) Cheese and turnips	(1) Coating (2) Coating	(1) 0.3% in accordance with Section B.01.047 (2) Good Manufacturing Practice in accordance with Section B.01.047
2-12-82	P.2	Petrolatum	(1) Bakery products (2) Fresh fruits and vegetables	(1) Release agent (2) Coating	(1) 0.15% in accordance with section B.01.047. If mineral oil is also used as a release agent the total of any combination of petrolatum and mineral oil must not exceed 0.15% (2) 0.3% in accordance with section B.01.047
11-10-84	P.2A	Polyethylene glycol (molecular weight range 3000-9000)	(1) Soft drinks (2) Table-top sweetener tablets containing aspartame (3) L-Lysine tablets	(1) Antifoaming agent (2) Lubricant (3) Tablet binder	(1) 10 p.p.m. (2) 1.0% (3) 7.0%
25-5-93	P.2B	Polydextrose	Unstandardized foods	Bodying and texturizing agent	Good Manufacturing Practice
11-5-06 5-5-83	P.3	Polyvinyl-pyrrolidone	(1) Ale; Beer; Cider; Light beer; Malt liquor; Porter; Stout; Wine (2) Table-top sweetener tablets containing aspartame (3) Colour lake dispersions for use in confectionery in tablet form	(1) Fining agent (2) Tablet binder (3) Viscosity reduction agent and stabilizer in colour lake dispersions	(1) 2 p.p.m. in the finished product (2) 0.3% (3) Good Manufacturing Practice (Residues of polyvinylpyrrolidone not to exceed 100 p.p.m. in the finished foods)
4-12-86					

	Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Purpose of Use*	*Column IV* *Maximum Level of Use*
25-8-76 1-3-94	P.4	Potassium Aluminium Sulphate	Flour; Whole wheat flour	Carrier of benzoyl peroxide	900 p.p.m. in accordance with subparagraphs B.13.001(e)(vi) and B.13.005(d)(vi)
11-5-06	P.4.1	Potassium Ferrocyanide	Wine	Fining agent	Good manufucturing Practice
14-5-96	P.5	Potassium Stearate	(1) Chewing gum (2) Emulsifying preparations containing propylene glycol monoesters	(1) Plasticizing agent (2) Stabilizing agent	(1) Good Manufacturing Practice (2) 2%
4-10-65	P.6	Propane	Unstandardized foods	Pressure dispensing and aerating agent	Good Manufacturing Practice
	P.7	Propylene Glycol	(1) Oil-soluble annatto (2) Unstandardized foods	(1) Solvent (2) Humectant	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
31-1-66	Q.1	Quillaia Extract	Beverage bases; Beverage mixes; Soft drinks	Foaming Agent	Good Manufacturing Practice
	S.1	Saponin	Beverage bases; Beverage mixes; Soft drinks	Foaming Agent	Good Manufacturing Practice
20-11-97	S.1.01	Silicon Dioxide	Edible vegetable oil-based cookware coating emulsions	Suspending agent	2.0% of preparation
17-10-88 14-2-91 31-1-91	S.1.1	Sodium Acid Pyro-phosphate	Frozen fish fillets; frozen minced fish; frozen lobster; frozen crab; frozen clams; frozen shrimp	To reduce processing losses and to reduce thaw drip	Used in combination with sodium tripolyphosphate and sodium pyrophosphate tetrabasic, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic
25-3-65 31-7-80	S.2	Sodium Aluminum Sulphate	Flour; Whole wheat flour	Carrier of benzoyl peroxide	900 p.p.m. in accordance with subparagraph B.13.001(e)(vi) and B.13.005(d)(vi)
	S.3	Sodium Bi-carbonate	(1) Confectionery (2) Salt	(1) Aerating agent (2) To stabilize potassium iodide in salt	(1) Good Manufacturing Practice (2) Good Manufacturing Practice

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
10-2-70	S.3A	Sodium carbonate	In combination with sodium hexameta-phosphate for use on frozen fish fillets, frozen lobster, frozen crabs, frozen clams and frozen shrimp	To reduce thaw drip	15% of the combination of sodium carbonate and sodium hexametaphosphate
27-4-78 12-11-81	S.3B	Sodium Carboxy-methyl cellulose	Sausage casings	Coatings to enable peeling	0.25% of the casing
15-11-94 16-11-78 4-6-92	S.4	Sodium Citrate	(1) Beef blood (2) Sour Cream (3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(1) Anticoagulant (2) Flavour precursor (3) To modify texture	(1) 0.5% (2) 0.1% (3) Good Manufacturing Practice
3-9-74 25-3-65	S.5	Sodium Ferrocyanide decahydrate	Dendritic salt	As an adjuvant in the production of dendritic salt crystals	13 p.p.m. calculated as anhydrous sodium ferrocyanide
31-1-91 10-2-70 17-11-77	S.6	Sodium Hexameta-phosphate	(1) Beef blood (2) Frozen fish filets; frozen lobsters; frozen crab; frozen clams and frozen shrimp (3) Gelatin intended for marshmallow compositions	(1) Anticoagulant (2) To reduce thaw drip (3) Whipping agent	(1) 0.2% (2) 0.5% total added phosphate calculated as sodium phosphate, dibasic (3) 2%
6-4-89	S.6A	Sodium Hydroxide	Frozen crustaceans and molluscs	To facilitate the removal of extraneous matter and to reduce moisture loss during cooking	When used in combination with sodium chloride (salt) and calcium oxide in solution, sodium hydroxide not to exceed 70 p.p.m.
24-4-77 17-11-77	S.6.1	Sodium Lauryl Sulphate	(1) Dried egg white (dried albumen) (2) Liquid egg white (liquid albumen); Frozen egg white (frozen albumen) (3) Gelatin intended for marshmallow compositions	(1) Whipping agent (2) Whipping agent (3) Whipping agent	(1) 0.1% (2) 0.0125% (3) 0.5%
28-4-77 23-1-74	S.6.2	Sodium potassium copper chlorophyllin	Breath freshener products in candy, tablet or gum form	To characterize the product	700 p.p.m.
9-9-70	S.7	Sodium Phosphate, dibasic	(1) Frozen fish (2) Frozen mushrooms	(1) To prevent cracking of glaze (2) To prevent discolouration	(1) Good Manufacturing Practice (2) Good Manufacturing Practice

*(R) Minor correction

TABLE VIII -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
17-10-88 14-2-91 31-1-91	S.7.1	Sodium Pyro-phosphate Tetrabasic	Frozen fish fillets; frozen minced fish; frozen lobster; frozen crab; frozen clams; frozen shrimp	To reduce processing losses and to reduce thaw drip	Used in combination with sodium tripolyphosphate and sodium acid pyrophosphate, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic
25-3-65	S.8	Sodium Silicate	Canned Drinking water	Corrosion Inhibitor	Good Manufacturing Practice
	S.9	Sodium Stearate	Chewing gum	Plasticizing agent	Good Manufacturing Practice
17-12-69 23-1-74	S.9A	Sodium Stearoyl-2-Lactylate	(1) Liquid and frozen egg-whites (2) Dried eggwhites (3) Oil toppings or topping mixes (4) Dehydrated potatoes	(1) Whipping agent (2) Whipping agent (3) Whipping agent (4) Conditioning agent	(1) 0.05% (2) 0.5% (3) 0.3% (4) 0.2% of dry weight
9-9-70	S.9B	Sodium Sulphate	Frozen mushrooms	To prevent discolouration	Good Manufacturing Practice
25-3-65	S.9C	Sodium Sulphite	Canned flaked tuna	To prevent discolouration	300 p.p.m.
	S.10	Sodium Thiosulphate	Salt	To stabilize potassium iodine in salt	Good Manufacturing Practice
24-8-72 31-1-91 17-10-88	S.11	Sodium Tripoly-phosphate	Frozen fish fillets; frozen minced fish; frozen comminuted fish; frozen lobster; frozen crab; frozen clams and frozen shrimp	To reduce processing losses and to reduce thaw drip	Used singly or in combination with sodium acid pyrophosphate and sodium pyrophosphate tetrabasic, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic

*(R) Minor correction

TABLE VIII -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
25-5-93	S.12	Revoked by P.C. 1993-1038 of May 25, 1993.			
	S.13	Stannous Chloride	(1) Asparagus packed in glass containers or fully-lined (lacquered) cans	(1) Flavour and colour stabilizer	(1) 25 p.p.m. calculated as tin
25-3-65 13-9-79 6-4-89			(2) Canned carbonated soft drinks; concentrated fruit juices except frozen concentrated orange juice; lemon juice; lime juice	(2) Flavour and colour stabilizer	(2) Good Manufacturing Practice
25-3-65	S.14	Stearic Acid	(1) Confectionery	(1) Release agent	(1) Good Manacturing Practice
			(2) Chewing gum	(2) Plasticizing agent	(2) Good Manufacturing Practice
11-10-84			(3) Foods sold in tablet form	(3) Release agent and lubricant	(3) Good Manufacturing Practice
8-9-66	S.15	Sodium Methyl Sulphate	Pectin	A processing aid, the result of methylation of pectin by sulfuric acid and methyl alcohol and neutralized by sodium bicarbonate	0.1% of pectin

*(R) Minor correction

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Purpose of Use	*Column IV* Maximum Level of Use
25-5-93	S.15A	Revoked by P.C. 1993-1038 of May 25, 1993.			
2-6-94	S.16	Sucrose Acetate Isobutyrate	(naming the flavour) Flavour for use in citrus-flavoured or spruce-flavoured beverages	Density adjusting agent	300 p.p.m. in citrus-flavoured or spruce-flavoured beverages as consumed
30-7-87	S.17	Sulphuric Acid	Coffee beans	To improve the extraction yield of coffee solids	Good Manufacturing Practice
18-10-79 25-10-05	T.1	Talc	(1) Rice (2) Chewing gum base (3) Chewing gum	(1) Coating agent (2) Filler (3) Dusting agent	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice
11-5-06	T.2	Tannic Acid	(1) Chewing gum (2) Cider; Honey wine; Wine	(1) To reduce adhesion (2) Fining agent	(1) Good Manufacturing Practice (2) 200 p.p.m.
25-5-93	T.2A	Revoked by P.C. 1993-1038 of May 25, 1993.			
27-4-78	T.3	Triacetin	Cake mixes	Wetting agent	Good Manufacturing Practice
	T.4	Triethyl Citrate	Liquid egg white (liquid albumen); Frozen egg white (frozen albumen)	Whipping agent	0.25%
25-5-93	X.1	Revoked by P.C. 1993-1038 of May 25, 1993.			

TABLE IX

FOOD ADDITIVES THAT MAY BE USED AS SWEETENERS

Item No.	*Column I* *Additive*	*Column II* *Permitted in or on*	*Column III* *Maximum Level of Use*
A.01	Acesulfame-potassium	(1) Table-top sweeteners	(1) Good Manufacturing Practice
		(2) Carbonated beverages	(2) 0.025% in beverages as consumed
		(3) Beverages; Beverage concentrates; Beverage mixes; Dairy beverages; (except for any of these products for which standards are set out in these Regulations)	(3) 0.05% in beverages as consumed
		(4) Desserts; Dessert mixes; Toppings; Topping mixes; Fillings; Filling mixes; (except for any of these products for which standards are set out in these Regulations)	(4) 0.1% in products as consumed
		(5) Chewing gum; Breath freshener products	(5) 0.35%
		(6) Fruit spreads (except for any of these products for which standards are set out in these Regulations)	(6) 0.1%
		(7) Salad dressings (except for any of these products for which standards are set out in these Regulations)	(7) 0.05%
		(8) Confectionery	(8) 0.25%
		(9) Bakery mixes; Bakery products; (except for any of these products for which standards are set out in these Regulations)	(9) 0.1% in products as consumed
A.1	Aspartame	(1) Table-top sweeteners	(1) Good Manufacturing Practice
		(2) Breakfast cereals	(2) 0.5%
		(3) Beverages; Beverage concentrates; Beverage mixes; (except for any of these products for which standards are set out in these Regulations)	(3) 0.1% in beverages as consumed
		(4) Desserts, Dessert mixes; Toppings; Topping mixes; Fillings; Filling mixes; (except for any of these products for which standards are set out in these Regulations)	(4) 0.3% in products as consumed
		(5) Chewing gum; Breath freshener products	(5) 1.0%
		(6) Fruit spreads; Purées and sauces; Table syrups; (except for any of these products for which standards are set out in these Regulations)	(6) 0.2%
		(7) Salad dressings; Peanut and other nut spreads; (except for any of these products for which standards are set out in these Regulations)	(7) 0.05%

6-10-94

25-5-93

*(R) Minor correction

	Item No.	*Column I* Additive	*Column II* Permitted in or on	*Column III* Maximum Level of Use
25-5-93	A.1	Aspartame (cont'd)	(8) Condiments (except for any of these products for which standards are set out in these Regulations) (9) Confectionery glazes for snack foods; Sweetened seasonings or coating mixes for snack foods (10) Confections and their coatings (except for any of these products for which standards are set out in these Regulations)	(8) 0.2% (9) 0.1% (10) 0.3%
25-5-93	A.2	Aspartame, encapsulated to prevent degradation during baking	Bakery products and baking mixes (except for any of these products for which standards are set out in these Regulations)	0.4% in product as consumed
23-11-04	E.1	Erythritol	(1) Table-top sweeteners (2) Dietetic beverages (3) Fat-based cream fillings and toppings (4) Dietetic cookies and wafers (5) Soft candies (6) Hard candies (7) Chewing gum	(1) Good Manufacturing Practice (2) 3.5% (3) 60% (4) 7% (5) 40% (6) 50% (7) 60%
20-11-97	H.1	Hydrogenated starch hydrolysates	Unstandardized foods	Good Manufacturing Practice
14-12-94	I.1	Isomalt	Unstandardized foods	Good Manufacturing Practice
	L.1	Lactitol	Unstandardized foods	Good Manufacturing Practice
25-5-93	M.1	Maltitol	Unstandardized foods	Good Manufacturing Practice
25-5-93	M.2	Maltitol syrup	Unstandardized foods	Good Manufacturing Practice
25-5-93	M.3	Mannitol	Unstandardized foods	Good Manufacturing Practice
25-5-93	S.1	Sorbitol	(1) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n) (2) Unstandardized foods	(1) 3.5% (2) Good Manufacturing Practice

TABLE IX -- (continued)
FOOD ADDITIVES THAT MAY BE USED AS SWEETENERS

Item No.	Column I Additive	Column II Permitted in or on	Column III Maximum Level of Use
20-11-97 S.1.1	Sorbitol syrup	Unstandardized foods	Good Manufacturing Practice
S.2	Sucralose	(1) Table-top sweeteners	(1) Good Manufacturing Practice
		(2) Breakfast cereals	(2) 0.1%
		(3) Beverages; Beverage concentrates; Beverage mixes; Dairy beverages; (except for any of these products for which standards are set out in these Regulations)	(3) 0.025% in beverages as consumed
		(4) Desserts; Dessert mixes; Toppings; Topping mixes; Dairy Desserts; Frozen Desserts; Fillings; Filling mixes; (except for any of these products for which standards are set out in these Regulations)	(4) 0.025% in products as consumed
25-5-93		(5) Chewing gum; Breath freshener products	(5) 0.15%
		(6) Fruit spreads (except for any of these products for which standards are set out in these Regulations)	(6) 0.045%
		(7) Salad dressings; Condiments; (except for any of these products for which standards are set out in these Regulations)	(7) 0.04%
		(8) Confections and their coatings; Confectionery glazes for snack foods; Sweetened seasonings or coating mixes for snack foods; (except for any of these products for which standards are set out in these Regulations)	(8) 0.07%
		(9) Baking mixes; Bakery products; (except for any of these products for which standards are set out in these Regulations)	(9) 0.065% in products as consumed
		(10) Processed fruit and vegetable products (except for any of these products for which standards are set out in these Regulations)	(10) 0.015%
		(11) Alcoholic beverages (except for any of these products for which standards are set out in these Regulations)	(11) 0.07%
		(12) Puddings; Pudding mixes	(12) 0.04% in products as consumed
		(13) Table syrups (except for any of these products for which standards are set out in these Regulations)	(13) 0.15%

*(R) Minor correction

TABLE IX -- (concluded)
FOOD ADDITIVES THAT MAY BE USED AS SWEETENERS

Item No.	Column I Additive	Column II Permitted in or on	Column III Maximum Level of Use
T.1	Thaumatin	(1) Chewing gum; Breath freshener products (2) Salt substitutes (3) (naming the flavour) Flavour referred to in section B.10.005; Unstandardized flavouring preparations	(1) 500 p.p.m. (2) 400 p.p.m. (3) 100 p.p.m.
X.1	Xylitol	Unstandardized foods	Good Manufacturing Practice

25-5-93

25-5-93

TABLE X

FOOD ADDITIVES THAT MAY BE USED AS PH ADJUSTING AGENTS, ACID-REACTING MATERIALS AND WATER CORRECTING AGENTS

	Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
18-10-79	A.1	Acetic Acid	(1) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese (2) Canned Asparagus (3) Gelatin (4) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice
	A.2	Adipic Acid	Unstandardized foods	Good Manufacturing Practice
	A.3	Ammonium Aluminum Sulphate	(1) Baking Powder (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
20-5-97 13-9-79	A.4	Ammonium Bicarbonate	(1) Cocoa products (2) Unstandardized foods	(1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 (2) Good Manufacturing Practice
20-5-97 13-9-79	A.5	Ammonium Carbonate	(1) Cocoa products (2) Unstandardized foods	(1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 (2) Good Manufacturing Practice
	A.6	Ammonium Citrate, dibasic	Unstandardized foods	Good Manufacturing Practice
	A.7	Ammonium Citrate, monobasic	Unstandardized foods	Good Manufacturing Practice
20-5-97 17-11-77 13-9-79	A.8	Ammonium Hydroxide	(1) Cocoa products (2) Gelatin (3) Unstandardized foods	(1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 (2) Good Manufacturing Practice (3) Good Manufacturing Practice

*(R) Minor correction

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
16-11-71 31-1-66	A.9	Ammonium Phosphate, dibasic	(1) Ale; Bacterial cultures; Baking powder; Beer; Light Beer; Malt liquor; Porter; Stout (2) Unstandardized bakery foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
16-11-71 31-1-66 5-11-74	A.10	Ammonium Phosphate, Monobasic	(1) Ale; Bacterial cultures; Baking Powder; Beer; Light beer; Malt liquor; Porter; Stout (2) Unstandardized bakery foods (3) Uncultured buttermilk	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) 0.1%
16-11-71	C.1	Calcium Acetate	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
13-5-75 18-10-79 4-12-86 20-5-97	C.2	Calcium Carbonate	(1) Ice cream mix; Ice milk mix; Wine (2) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese (3) Grape Juice (4) Unstandardized foods (5) Cocoa products	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005
16-11-71	C.3	Calcium Chloride	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
10-11-76	C.4	Calcium Citrate	(1) Infant formula (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
	C.5	Calcium Fumarate	Unstandardized Foods	Good Manufacturing Practice

*(R) Minor correction

TABLE X -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	C.6	Calcium Gluconate	Unstandardized foods	Good Manufacturing Practice
16-11-71 9-8-67 4-12-86	C.7	Calcium Hydroxide	(1) Ale; Beer; Ice cream mix; Ice milk mix; Light beer; Malt liquor; Porter; Stout (2) Canned peas (3) Infant formula (4) Grape Juice (5) Unstandardized foods	(1) Good Manufacturing Practice (2) 0.01% (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice
	C.8	Calcium Lactate	(1) Baking Powder (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
13-5-75	C.9	Calcium Oxide	(1) Ale; Beer; Ice cream mix; Ice milk mix; Light beer; Malt liquor; Porter; Stout (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
	C.10	Calcium Phosphate, dibasic	Unstandardized foods	Good Manufacturing Practice
16-11-71	C.11	Calcium Phosphate, monobasic	(1) Ale; Baking powder; Beer; Light beer; Malt liquor; Porter; Stout (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
	C.12	Calcium Phosphate, tribasic	Unstandardized foods	Good Manufacturing Practice
16-11-71	C.13	Calcium Sulphate	Ale; Beer; Light beer; Malt liquor; Porter; Stout; Wine	Good Manufacturing Practice
1-3-01	C.13A	Carbon Dioxide	(Naming the variety) Cheese	Good Manufacturing Practice

*(R) Minor correction

TABLE X -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	C.14	Citric Acid	(1) Ale; Apple (or rhubarb) and (naming the fruit) Jam; Apricot nectar; Beer; Canned artichokes; Canned asparagus; Canned bean sprouts; Canned chili peppers; Canned mushrooms; Canned onions;	(1) Good Manufacturing Practice
13-9-79			Canned pears; Canned shellfish; Canned spring mackerel; Cider; Cottage cheese; Creamed cottage cheese; Egg white (albumen) and Yolk; Liquid, dried or frozen whole egg; Fig marmalade; Fig marmalade with pectin; French dressing; Frozen	
30-8-95			cooked shrimp; Frozen (naming the fruit); Gelatin; Grape juice; Honey wine; Ice cream mix; Ice milk mix;	
13-9-79			(naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; Light beer; Malt liquor; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Mayonnaise;	
9-12-97			Mincemeat; Olives; Peach nectar; Pear nectar; Pineapple marmalade; Pineapple marmalade with pectin; Porter; Salad dressing; Sherbet; Stout; Tomatoes; Wine	
			(2) Canned applesauce; Canned grapefruit; Canned mandarin oranges; Canned pears; Canned pineapple; Canned strawberries	(2) Sufficient to maintain pH 4.2 to 4.5
			(3) Infant formula	(3) Good Manufacturing Practice
			(4) Margarine	(4) Good Manufacturing Practice
			(5) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processes cheese food;	(5) Good Manufacturing Practice
18-10-79			Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese	
20-5-97			(6) Unstandardized foods	(6) Good Manufacturing Practice
			(7) Cocoa products	(7) 1%, singly or in combination with tartaric acid, calculated on a fat-free basis

*(R) Minor correction

TABLE X -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
17-11-77	C.15	Cream of Tartar	Same Foods as listed for Potassium Acid Tartrate	Same levels as prescribed for Potassium Acid Tartrate.
11-5-06	F.1	Fumaric Acid	(1) Gelatin (2) Unstandardized foods (3) Wine	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice
	G.1	Gluconic Acid	Unstandardized foods	Good Manufacturing Practice
	G.2	Glucono-deltalactone	Unstandardized foods	Good Manufacturing Practice
17-11-77 10-11-76	H.1	Hydrochloric Acid	(1) Ale; Beer; Gelatine; Light beer; Malt liquor; Porter; Stout (2) Infant formula	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
28-4-77 17-11-77 18-10-79 11-5-06	L.1	Lactic acid	(1) Ale; Baking powder; Beer; Bread; Cider; Cottage cheese; Creamed cottage cheese; Egg white (albumen) and yolk; Liquid, dried or frozen whole egg; French dressing; Ice cream mix; Ice milk mix; Light beer; Malt liquor; Mayonnaise; Olives; Pickles and Relishes; Porter; Salad dressing; Sherbet; Stout (2) Canned pears; Canned strawberries. (3) Margarine (4) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese (5) Unstandardized foods (6) Wine	(1) Good Manufacturing Practice (2) Sufficient to maintain pH 4.2 to 4.5 (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice (6) Good Manufacturing Practice
20-5-97 13-9-79	M.2	Magnesium Carbonate	(1) Cocoa products (2) Ice cream mix; Ice milk mix (3) Unstandardized foods	(1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 (2) Good Manufacturing Practice (3) Good Manufacturing Practice

TABLE X -- (continued)

Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
M.3	Magnesium Citrate	Soft drinks	Good Manufacturing Practice
M.4	Magnesium Fumarate	Unstandardized foods	Good Manufacturing Practice
M.5	Magnesium Hydroxide	(1) Canned peas (2) Cocoa products (3) Gelatin; Ice cream mix; Ice milk mix (4) Bacterial cultures	(1) 0.05% (2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 (3) Good Manufacturing Practice (4) Good Manufacturing Practice

9-8-67
20-5-97

26-6-80
13-6-95

*(R) Minor correction

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
13-5-75	M.6	Magnesium Oxide	Ice cream mix; Ice milk mix	Good Manufacturing Practice
13-6-95	M.6A	Magnesium Phosphate	Bacterial cultures	Good Manufacturing Practice
13-6-95	M.7	Magnesium Sulphate	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout (2) Bacterial cultures	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
13-9-79 30-8-95 13-9-79 17-11-77 18-10-79	M.8	Malic Acid	(1) Apple (or rhubarb) and (naming the fruit) Jam; Apricot nectar; Canned asparagus; Fig marmalade; Fig marmalade with pectin; Frozen (naming the fruit); (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Peach nectar; Pear nectar; Pineapple marmalade; Pineapple marmalade with pectin (2) Canned applesauce; Canned pears; Canned strawberries (3) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese (4) Unstandardized foods (5) Wine	(1) Good Manufacturing Practice (2) Sufficient to maintain pH 4.2 to 4.5 (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice
11-5-06				
13-6-95	M.8A	Manganese Sulphate	Bacterial cultures	Good Manufacturing Practice
11-5-06	M.9	Metatartaric Acid	Wine	0.01%
20-5-97	P.1	Phosphoric Acid	(1) Ale; Beer; Cottage Cheese; Creamed cottage cheese; Gelatin; Light beer; Malt liquor; Mono-glycerides and mono- and diglycerides; Porter; Stout	(1) Good Manufacturing Practice

TABLE X -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
16-9-70	P.1	Phosphoric Acid (cont'd.)	(2) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese	(2) Good Manufacturing Practice
18-10-79			(3) Fish protein	(3) Good Manufacturing Practice
20-5-97			(4) Unstandardized foods	(4) Good Manufacturing Practice
			(5) Cocoa products	(5) 0.5%, expressed as P_2O_5, calculated on a fat-free basis
23-1-74	P.2	Potassium Acid Tartrate	(1) Baking powder; Honey wine	(1) Good Manufacturing Practice
			(2) Unstandardized foods	(2) Good Manufacturing Practice
11-5-06			(3) Wine	(3) 0.42 %
	P.3	Potassium Aluminum Sulphate	(1) Ale; Baking powder; Beer; Light beer; Malt liquor; Oil-soluble annatto; Porter; Stout;	(1) Good Manufacturing Practice
16-11-71			(2) Unstandardized foods	(2) Good Manufacturing Practice
	P.4	Potassium Bicarbonate	(1) Baking powder; Malted milk; Malted milk powder	(1) Good Manufacturing Practice
17-11-77				
20-5-97			(2) Cocoa products	(2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005
18-10-79			(3) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese	(3) Good Manufacturing Practice
13-9-79			(4) Infant formula	(4) Good Manufacturing Practice
			(5) Margarine	(5) Good Manufacturing Practice
			(6) Unstandardized foods	(6) Good Manufacturing Practice
11-5-06			(7) Wine	(7) Good Manufacturing Practice

TABLE X -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
20-5-97	P.5	Potassium Carbonate	(1) Cocoa products	(1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005
17-11-77			(2) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese foods; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese	(2) Good Manufacturing Practice
18-10-79			(3) Margarine	(3) Good Manufacturing Practice
4-6-92			(4) Unstandardized foods	(4) Good Manufacturing Practice
			(5) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(5) Good Manufacturing Practice
11-5-06			(6) Wine	(6) Good Manufacturing Practice
16-11-71	P.6	Potassium Chloride	Ale; Beer; Light beer; Malt liquor; Porter; Stout;	Good Manufacturing Practice
17-11-77	P.7	Potassium Citrate	(1) Infant formula	(1) Good Manufacturing Practice
			(2) Margarine	(2) Good Manufacturing Practice
			(3) Unstandardized foods	(3) Good Manufacturing Practice
11-5-06			(4) Wine	(4) Good Manufacturing Practice

TABLE X -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
P.8	Potassium Fumarate	Unstandardized foods	Good Manufacturing Practice
P.9 20-5-97 13-9-79 4-12-86	Potassium Hydroxide	(1) Oil-soluble annatto (2) Cocoa products (3) Ice cream mix; Ice milk mix; Pumping pickle; Cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product (Division 14 only) (4) Infant formula (5) Margarine (6) Grape juice (7) Unstandardized foods	(1) 1.0% (2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice (6) Good Manufacturing Practice (7) Good Manufacturing Practice
P.9A 17-11-77	Potassium Lactate	Margarine	Good Manufacturing Practice
P.10 25-3-65	Potassium Phosphate, dibasic	Unstandardized foods	Good Manufacturing Practice
P.11 16-11-71	Potassium Sulphate	Ale; Beer; Light beer; Malt liquor; Porter; Soft drinks; Stout	Good Manufacturing Practice
P.12 25-8-76	Potassium Tartrate	Cider	Good Manufacturing Practice
S.1	Sodium Acetate	Unstandardized foods	Good Manufacturing Practice
S.2	Sodium Acid Pyrophos-phate	(1) Baking powder (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
S.3	Sodium Acid Tartrate	Baking powder	Good Manufacturing Practice
S.4 4-10-65	Sodium Aluminum Phosphate	Unstandardized foods	Good Manufacturing Practice
S.5	Sodium Aluminum Sulphate	(1) Baking powder (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice

*(R) Minor correction

TABLE X -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
S.6	Sodium Bicarbonate	(1) Apple (or rhubarb) and (naming the fruit) jam; Baking powder; Egg white (albumen) and yolk; Liquid, dried or frozen whole egg; Ice cream mix; Ice milk mix; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly; (naming the fruit) jelly with pectin; Malted milk powder; (naming the citrus fruit) marmalade; (naming the citrus fruit) marmalade with pectin; Oil-soluble annatto; Pineapple marmalade or fig marmalade; Pineapple marmalade with pectin or fig marmalade with pectin; Pumping pickle; Cover pickle and dry cure employed in the curing of preserved meat (Division 14) or preserved meat by-product	(1) Good Manufacturing Practice
6-2-92			
13-9-79			
20-5-97		(2) Cocoa products	(2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005
		(3) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese	(3) Good Manufacturing Practice
		(4) Infant formula	(4) Good Manufacturing Practice
		(5) Margarine	(5) Good Manufacturing Practice
		(6) Unstandardized foods	(6) Good Manufacturing Practice
S.7	Sodium Bisulphate	Ale; Beer; Light beer; Malt liquor; Porter; Stout	Good Manufacturing Practice
16-11-66			

*(R) Minor correction

TABLE X -- (continued)

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
	S.8	Sodium Carbonate	(1) Apple (or rhubarb) and (naming the fruit) Jam; Egg white (albumen) and yolk; Liquid, dried or frozen whole egg; Gelatin; Ice cream mix; Ice milk mix; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Meat binder for preserved meat and preserved meat by-product (Division 14 only); Pineapple marmalade or fig marmalade; Pineapple marmalade with pectin or fig marmalade with pectin	(1) Good Manufacturing Practice
13-9-79 17-11-77				
20-5-97			(2) Cocoa products	(2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005
18-10-79			(3) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese	(3) Good Manufacturing Practice
			(4) Margarine	(4) Good Manufacturing Practice
			(5) Unstandardized foods	(5) Good Manufacturing Practice

*(R) Minor correction

TABLE X -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	S.9	Sodium Citrate	(1) Apple (or rhubarb and (naming the fruit) Jam; Cottage cheese; Cream; Creamed cottage cheese; Ice cream mix; Ice milk mix; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Pineapple Marmalade or Fig Marmalade; Pineapple Marmalade with pectin or Fig Marmalade with pectin; Sherbet	(1) Good Manufacturing Practice
10-11-76			(2) Infant formula	(2) Good Manufacturing Practice
17-11-77			(3) Unstandardized foods	(3) Good Manufacturing Practice
			(4) Margarine	(4) Good Manufacturing Practice
	S.12	Sodium Fumarate	Unstandardized foods	Good Manufacturing Practice
	S.13	Sodium Gluconate	Unstandardized foods	Good Manufacturing Practice
	S.14	Sodium Hexameta-phosphate	Unstandardized foods	Good Manufacturing Practice
20-5-97	S.15	Sodium Hydroxide	(1) Cocoa products	(1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005
17-11-77			(2) Gelatin; Ice cream mix; Ice milk mix; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; Pumping pickle; Cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product (Division 14 only)	(2) Good Manufacturing Practice
13-9-79			(3) Infant formula	(3) Good Manufacturing Practice
			(4) Margarine	(4) Good Manufacturing Practice
			(5) Unstandardized foods	(5) Good Manufacturing Practice
17-11-77	S.16	Sodium Lactate	(1) Margarine	(1) Good Manufacturing Practice
			(2) Unstandardized foods	(2) Good Manufacturing Practice
	S.17	Sodium Phosphate, dibasic	(1) Ale; Bacterial culture; Beer; Cream; Light beer; Malt liquor; Porter; Stout	(1) Good Manufacturing Practice
16-11-71			(2) Unstandardized foods	(2) Good Manufacturing Practice

*(R) Minor correction

TABLE X -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
16-11-71	S.18	Sodium Phosphate, monobasic	(1) Ale; Beer; Light beer; Malt liquor; Porter, Stout (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
16-11-71	S.19	Sodium Phosphate, tribasic	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
25-3-65 17-11-77	S.20	Sodium Potassium Tartrate	(1) Apple (or Rhubarb) and (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; naming the citrus fruit) Marmalade with pectin; Pineapple Marmalade or Fig Marmalade; Pineapple Marmalade with pectin or Fig Marmalade with pectin (2) Unstandardized foods (3) Margarine	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice
	S.21	Sodium Pyrophosphate, tetrabasic	Unstandardized foods	Good Manufacturing Practice
	S.22	Sodium Tripoly-phosphate	Unstandardized foods	Good Manufacturing Practice
16-11-71	S.23	Sulphuric Acid	Ale; Beer; Light beer; Malt liquor; Porter; Stout	Good Manufacturing Practice
17-11-77	S.24	Sulphurous Acid	Gelatin	Good Manufacturing Practice provided the finished product does not contain more than 500 p.p.m. calculated as sulphur dioxide

*(R) Minor correction

TABLE X -- (concluded)

Item No.	Column I Additive	Column II Permitted in or Upon	Column II Maximum Level of Use
	T.1	Tartaric Acid	(1) Ale; Apple (or rhubarb) and (naming the fruit) Jam; Baking powder; Beer; Cider; Canned asparagus; Fig marmalade; Fig marmalade with pectin; French dressing; Honey wine; Ice cream mix; Ice cream mix; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; Light beer; Malt liquor; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Mayonnaise; Pineapple marmalade; Pineapple marmalade with pectin; Porter; Salad dressing; Sherbet; Stout; Wine	(1) Good Manufacturing Practice
13-9-79 17-11-77		(2) Canned pears; Canned strawberries	(2) Sufficient to maintain pH 4.2 to 4.5
		(3) Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients); (named variety) Whey cheese	(3) Good Manufacturing Practice
18-10-79		(4) Margarine	(4) Good Manufacturing Practice
		(5) Unstandardized foods	(5) Good Manufacturing Practice
20-5-97		(6) Cocoa products	(6) 1%, singly or in combination with citric acid, calculated on a fat-free basis

*(R) Minor correction

TABLE XI

PART I

FOOD ADDITIVES THAT MAY BE USED AS CLASS I PRESERVATIVES

Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
A.1	Acetic Acid	(1) Preserved fish; Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Pumping pickle; Cover pickle and Dry cure employed in the curing of preserved meat or preserved meat by-product	(1) Good Manufacturing Practice
		(2) Unstandardized foods	(2) Good Manufacturing Practice
A.2	Ascorbic Acid	(1) Ale; Beer; Canned mushrooms; Canned tuna; Canned white asparagus; Cider; Frozen fruit; Glaze of frozen fish; Headcheese; Light beer; Malt liquor; Meat binder for preserved meat and preserved meat by-product (Division 14 only); Porter; Preserved fish; Frozen minced fish; Frozen comminuted fish; Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Pumping pickle; Cover pickle and Dry cure employed in the curing of preserved meat or preserved meat by-product; Stout; Wine	(1) Good Manufacturing Practice
13-9-79			
25-8-76		(2) Canned applesauce	(2) If used either singly or in combination with Iso-Ascorbic Acid, the total not to exceed 150 p.p.m.
17-11-77		(3) Canned peaches	(3) 550 p.p.m.
		(4) Unstandardized foods	(4) Good Manufacturing Practice
C.1	Calcium Ascorbate	Same foods as listed for Ascorbic Acid	Same levels as prescribed for Ascorbic Acid

TABLE XI

PART I -- (continued)

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
26-6-80 25-8-76 17-11-77	E.1	Erythorbic Acid	(1) Ale; Beer; Cider; Frozen fruit; Headcheese; Light beer; Malt liquor; Meat binder for preserved meat and preserved meat by-product (Division 14 only); Porter; Preserved fish; Frozen minced fish; Frozen comminuted fish; Glace of frozen fish; Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Pumping pickle; Cover pickle and Dry cure employed in the curing of preserved meat or preserved meat by-product; Stout; Wine (2) Canned applesauce (3) Unstandardized foods	(1) Good Manufacturing Practice (2) If used either singly or in combination with Ascorbic Acid, the total not to exceed 150 p.p.m. (3) Good Manufacturing Practice
	I.1	Iso-Ascorbic Acid	Same foods as listed for Erythorbic Acid	Same levels as prescribed for Erythorbic Acid

TABLE XI

PART I -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
P.1	Potassium Nitrate	(1) Meat binder for dry sausage, semi-dry sausage, preserved meat and preserved meat by-products prepared by slow cure processes (Division 14)	(1) When the meat binder is used in accordance with label instructions, whether potassium nitrate is added alone or in combination with sodium nitrate, the total amount of such nitrates thereby added to each batch of dry sausage, semi-dry sausage, preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation.
22-3-79		(2) Cover pickle and dry cure employed in the curing of preserved meat and preserved meat by-products prepared by slow cure processes (Division 14)	(2) When the cover pickle or dry cure is used in accordance with label instructions, whether potassium nitrate is added alone or in combination with sodium nitrate, the total amount of such nitrates there-by added to each batch of preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation
8-4-75			
		(3) Dry sausage, semi-dry sausage, preserved meat and preserved meat by-products prepared by slow cure processes (Division 14)	(3) Where potassium nitrate is added alone or in combination with sodium nitrate, the total amount of such nitrates added to each batch of dry sausage, semi-dry sausage, preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation
3-2-77			
		(4) Ripened cheese, containing not more than 68% moisture on a fat free basis during manufacture of which the lactic acid fermentation and salting is completed later than 12 hours after coagulation of the curd by food enzymes and where the added salt is applied externally to the cheese as dry salt or in the form of brine	(4) If used singly or in combination with sodium nitrate, the total not to exceed 200 p.p.m. (based in milk). Residue in the finished cheese not to exceed 50 p.p.m.
3-2-77			

*(R) Minor correction

TABLE XI

PART I -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
P.1	Potassium Nitrate (conc.)	(5) Mold ripened cheese packed in hermetically sealed containers	(5) If used singly or in combination with sodium nitrate, the total not to exceed 200 p.p.m. (based in milk). Residue in the finished cheese not to exceed 50 p.p.m.
P.2	Potassium Nitrite	(1) Meat binder, pumping pickle, cover pickle and dry cure employed in the curing or preserved meat and preserved meat by-products (Division 14)	(1) When the meat binder, pumping pickle, cover pickle or dry cure is used in accordance with label instructions, whether potassium nitrite is added alone or in combination with sodium nitrite, the total amount of such nitrites there-by added to each batch of preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million calculated prior to any smoking, cooking or fermentation.
		(2) Preserved meat except side bacon and preserved meat by-products (Division 14)	(2) Where potassium nitrite is added alone or in combination with sodium nitrite, the total amount of such nitrites added to each batch of preserved meat, except side bacon or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation.
		(3) Side bacon	(3) Where potassium nitrite is added alone or in combination with sodium nitrite, the total amount of such nitrites added to each batch of side bacon shall not exceed 0.19 ounce per 100 pounds or 120 parts per million, calculated prior to any smoking, cooking or fermentation.
		(4) Preserved poultry meat and preserved poultry meat by-products (Division 22)	(4) Where potassium nitrite is added alone or in combination with sodium nitrite, the total amount of such nitrites added to each batch of preserved poultry meat or preserved poultry meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation.

3-2-77

8-4-75

22-3-79

5-3-87

PART I -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	S.1 Sodium Ascorbate	Same foods as listed for Ascorbic Acid	Same levels as prescribed for Ascorbic Acid.
25-10-05	S.2 Sodium Erythorbate	(1) Same foods as listed for Erythorbic Acid (2) Canned clams	(1) Same levels as prescribed for Erythorbic Acid (2) 350 p.p.m.
24-8-72	S.3 Sodium Iso-Ascorbate	Same foods as listed for Erythorbic Acid	Same levels as prescribed for Erythorbic Acid.
	S.4 Sodium Nitrate	(1) Meat binder for dry sausage, semi-dry sausage, preserved meat and preserved meat by-products prepared by slow cure processes (Division 14)	(1) When the meat binder is used in accordance with label instructions, whether sodium nitrate is added alone or in combination with potassium nitrate, the total amount of such nitrates thereby added to each batch of dry sausage, semi-dry sausage, preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation.
8-4-75		(2) Cover pickle and dry cure employed in the curing of preserved meat and preserved meat by-products prepared by slow cure processes (Division 14)	(2) When the cover pickle or dry cure is used in accordance with label instructions, whether sodium nitrate is added alone or in combination with potassium nitrate, the total amount of such nitrates thereby added to each batch of preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation.
22-3-79		(3) Dry sausage, semi-dry sausage, preserved meat and preserved meat by-products prepared by the slow cure processes (Division 14)	(3) Where sodium nitrate is added alone or in combination with potassium nitrate, the total amount of such nitrates added to each batch of dry sausage, semi-dry sausage, preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking or fermentation.

TABLE XI

PART I -- (continued)

Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
S.4	Sodium Nitrate (conc.)	(4) Ripened cheese, containing not more than 68% moisture on a fat free basis during manufacture of which the lactic acid fermentation and salting is completed later than 12 hours after coagulation of the curd by food enzymes and where the added salt is applied externally to the cheese as dry salt or in the form of brine (5) Mold ripened cheese packed in hermetically sealed containers	(4) If singly or in combination with potassium nitrate, the total not to exceed 200 p.p.m. (based in milk). Residue in the finished cheese not to exceed 50 p.p.m. (5) If used singly or in combination with potassium nitrate, the total not to exceed 200 p.p.m. (based in milk). Residue in the finished cheese not to exceed 50 p.p.m.

3-2-77

*(R) Minor correction

TABLE XI

PART I -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
S.5	Sodium Nitrite	(1) Meat binder, pumping pickle, cover pickle and dry cure employed in the curing of preserved meat and preserved meat by-products (Division 14)	(1) When the meat binder, pumping pickle, cover pickle or dry cure is used in accordance with label instructions, whether sodium nitrite is added alone or in combination with potassium nitrite, the total amount of such nitrites thereby added to each batch of preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation.
22-3-79			
		(2) Preserved meat, except side bacon, and preserved meat by-products (Division 14)	(2) Where sodium nitrite is added alone or in combination with potassium nitrite, the total amount of such nitrites added to each batch of preserved meat, except side bacon or preserved meat by-products, shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation.
8-4-75			
		(3) Side bacon	(3) Where sodium nitrite is added alone or in combination with potassium nitrite, the total amount of such nitrites added to each batch of side bacon shall not exceed 0.19 ounce per 100 pounds or 120 parts per million, calculated prior to any smoking, cooking or fermentation.
5-3-87			
		(4) Preserved poultry meat and preserved poultry meat by-products (Division 22)	(4) Where sodium nitrite is added alone or in combination with potassium nitrite, the total amount of such nitrites added to each batch of preserved poultry meat or preserved poultry meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation.
22-3-79			

*(R) Minor correction

TABLE XI

PART I -- (concluded)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
W.1	Wood Smoke	(1) (named variety) Cheese; Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(1) Good Manufacturing Practice
		(2) Preserved fish; Preserved meat (Division 14 and 21); Preserved meat by-products (Division 14 and 21); Preserved poultry meat; Preserved poultry meat by-product; Sausage	(2) Good Manufacturing Practice
		(3) Unstandardized foods	(3) Good Manufacturing Practice

18-10-79

*(R) Minor correction

PART II

FOOD ADDITIVES THAT MAY BE USED AS CLASS II PRESERVATIVES

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
19-3-97	B.1	Benzoic Acid	(1) Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; Fruit juices except frozen concentrated orange juice; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Marinated or similar cold-processed packaged fish and meat (Division 21); (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; Tomato catsup; Tomato paste; tomato pulp; Tomato puree	(1) 1,000 p.p.m.
6-4-89 19-3-97			(2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(2) 1,000 p.p.m.
17-11-77			(3) Margarine	(3) If used singly or in combination with Sorbic Acid, the total shall not exceed 1,000 p.p.m.
31-1-91	C.1	Calcium Sorbate	Same foods as listed for Sorbic Acid	Same levels prescribed for Sorbic Acid
15-9-98	H.1	4-Hexyl-resorcinol	Crustaceans	Good Manufacturing Practice. Residues in the edible portion of the uncooked product not to exceed 1.0 p.p.m.
19-3-97	M.1	Methyl-p-hydroxy Benzoate	(1) Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; Fruit juices except frozen concentrated orange juice; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Marinated or similar cold-processed packaged fish and meat (Division 21); (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; Tomato catsup; Tomato paste; Tomato pulp; Tomato puree	(1) 1,000 p.p.m.
6-4-89			(2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Division 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(2) 1,000 p.p.m.

*(R) Minor correction

TABLE XI

PART II -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	M.2	Methyl Paraben	Same foods as listed for Methyl-p-hydroxy Benzoate	Same levels as prescribed for methyl-p-hydroxy Benzoate
10-1-86 19-3-97	P.1	Potassium Benzoate	Same foods as listed for Benzoic Acid	1,000 p.p.m. calculated as Benzoic Acid
10-1-86	P.2	Potassium Bisulphite	Same foods as listed for Sulphurous Acid	Same levels as prescribed for Sulphurous Acid
10-1-86	P.3.	Potassium Meta-bisulphite	Same foods as listed for Sulphurous Acid	Same levels as prescribed for Sulphurous Acid
8-4-75 31-1-91	P.4	Potassium Sorbate	Same foods as listed for Sorbic Acid	Same levels as prescribed for Sorbic Acid
10-1-86 19-3-97 6-4-89 19-3-97	P.5	Propyl-*p*-hydroxy Benzoate	(1) Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; Fruit juices except frozen concentrated orange juice; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; marinated or similar cold-processed packaged fish and meat (Division 21); (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; Tomato catsup; Tomato paste; Tomato pulp; Tomato puree (2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Division 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(1) 1,000 p.p.m. (2) 1,000 p.p.m.

*(R) Minor correction

TABLE XI

PART II -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
10-1-86	P.6	Propyl Paraben	Same foods as listed for Propyl-p-hydroxy Benzoate	Same levels as prescribed for propyl-p-hydroxy Benzoate
19-3-97	S.1	Sodium Benzoate	Same foods as listed for Benzoic Acid	1,000 p.p.m. calculated as Benzoic Acid
	S.2	Sodium Bisulphite	Same foods as listed for Sulphurous Acid	Same levels as prescribed for Sulphurous Acid
	S.3	Sodium Meta-bisulphite	Same foods as listed for Sulphurous Acid	Same levels as prescribed for Sulphurous Acid
19-3-97	S.4	Sodium Salt of Methyl-p-hydroxy Benzoic Acid	Same foods as listed for Methyl-p-hydrozy Benzoate	1,000 p.p.m. calculated as Methyl-p-hydroxy Benzoate
19-3-97	S.5	Sodium Salt of Propyl-p-hydroxy Benzoic Acid	Same foods as listed for Propyl-p-hydroxy Benzoate	1,000 p.p.m. as calculated as Propyl-p-hydroxy Benzoate
8-4-75 31-1-91	S.6	Sodium Sorbate	Same foods as listed for Sorbic Acid	Same levels as prescribed for Sorbic Acid
	S.7	Sodium Sulphite	Same foods as listed for Sulphurous Acid	Same levels as prescribed for Sulphurous Acid
	S.8	Sodium Dithionite	Same foods as listed for Sulphurous Acid	Same levels as prescribed for Sulphurous Acid

*(R) Minor correction

TABLE XI

PART II -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	S.9	Sorbic Acid	(1) Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; Fruit juices except frozen concentrated orange juice; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; Smoked or salted dried fish; Smoked or salted fish paste; (naming the source of the glucose) syrup; Tomato catsup; Tomato paste; Tomato pulp; Tomato puree	(1) 1,000 p.p.m.
23-11-67 6-4-89				
8-4-75 17-11-77 30-7-87			(2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(2) 1,000 p.p.m.
			(3) Olive brine	(3) 300 p.p.m.
			(4) Margarine	(4) If used singly or in combination with Benzoic acid the total shall not exceed 1,000 p.p.m.
13-12-95			(5) Unstandardized salad dressings	(5) 3350 p.p.m.
	S.10	Sulphurous Acid	(1) Cider; Honey wine; Wine	(1) 70 p.p.m. in the free state or 350 p.p.m. in the combined state calculated as sulphur dioxide
25-8-76 19-3-97				
19-3-97			(2) Ale; Beer; Light beer; Malt liquor; Porter; Stout	(2) 15 p.p.m. calculated as sulphur dioxide
19-3-97				(3) 500 p.p.m. calculated as sulphur dioxide
17-11-77 6-4-89			(3) Apple (or rhubarb) and (naming the fruit) jam; Fancy molasses; Fig marmalade with pectin; Frozen sliced apples; Fruit juices except frozen concentrated orange juice; Gelatin; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; (naming the source of the glucose) syrup; Refiners' molasses; Table molasses; Tomato catsup; Tomato paste; Tomato pulp; Tomato puree	

*(R) Minor correction

TABLE XI

PART II -- (concluded)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
S.10	Sulphurous Acid - (conc.)	(4) Beverages	(4) 100 p.p.m calculated as sulphur dioxide
		(5) Dried fruits and vegetables	(5) 2,500 p.p.m. calculated as sulphur dioxide
		(6) Unstandardized foods [except in food recognized as a source of thiamine and except unstandardized preparation of (a) meat and meat by-product (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(6) 500 p.p.m. calculated as sulphur dioxide
9-9-70		(7) Frozen mushrooms	(7) 90 p.p.m. calculated as sulphur dioxide
		(8) Dextrose, Anhydrous; Dextrose Monohydrate	(8) 20 p.p.m. calculated as sulphur dioxide
26-2-76		(9) Glucose or glucose syrup	(9) 40 p.p.m. except glucose or glucose syrup for the manufacture of sugar confectionery not more than 400 p.p.m. calculated as sulphur dioxide
		(10) Glucose solids or dried glucose syrup	(10) 40 p.p.m. except glucose solids or dried glucose syrup for the manufacture of sugar confectionery not more than 150 p.p.m. calculated as sulphur dioxide
9-10-86		(11) Crustaceans	(11) Good Manufacturing Practice. Residues in the edible portion of the uncooked product not to exceed 100 p.p.m., calculated as sulphur dioxide

*(R) Minor correction

PART III

FOOD ADDITIVES THAT MAY BE USED AS CLASS III PRESERVATIVES

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
25-10-05	C.1	Calcium Propionate	(1) Same foods as listed for Propionic Acid (2) Soft flour tortillas	(1) 2,000 p.p.m. calculated as Propionic Acid (2) 4,000 p.p.m.
23-11-67	C.2	Calcium Sorbate	Same foods as listed for Sorbic Acid	Same maximum levels of use as listed for Sorbic Acid.
8-4-97 1-4-82	N.1	Natamycin	(1) The surface of (named variety) cheese and cheddar cheese (2) The surface of grated or shredded (named variety) cheese and grated or shredded cheddar cheese	(1) 20 p.p.m. in accordance with the requirements of sections B.08.033 and B.08.034 (2) 10 p.p.m. in accordance with the requirements of sections B.08.033 and B.08.034
25-10-05 23-11-67	P.1	Potassium Sorbate	(1) Same foods as listed for Sorbic Acid (2) Soft flour tortillas	(1) Same maximum levels of use as listed for Sorbic Acid (2) 5,000 p.p.m.
18-10-79	P.2	Propionic Acid	(1) Bread (2) (named variety) Cheese; Cheddar cheese; Cream cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients) (3) Unstandardized foods except unstandardized preparations of (a) Meat and meat by-product (Division 14 and 21); (b) fish; and (c) poultry meat, and poultry meat by-products	(1) 2,000 p.p.m (2) 2,000 p.p.m. or 3,000 p.p.m., as the case may be, in accordance with the requirements of sections B.08.033, B.08.034, B.08.035, B.08.037, B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2 B.08.041.3, B.08.041.4, B.08.041.5, B.08.041.6, B.08.041.7, B.08.041.08 (3) 2,000 p.p.m

TABLE XI

PART III -- (concluded)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
18-10-79	S.1 Sodium Diacetate	(1) Bread (2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(1) 3,000 p.p.m. (2) 3,000 p.p.m.
	S.2 Sodium Propionate	Same foods as listed for Propionic Acid	2,000 p.p.m. calculated as Propionic Acid
	S.3 Sodium Sorbate	Same foods as listed for Sorbic Acid	Same maximum levels of use as listed for Sorbic Acid
23-11-67 25-3-65 25-8-76 18-10-79 9-7-81	S.4 Sorbic Acid	(1) Bread (2) (named variety) Cheese; Cheddar cheese; Cream cheese; Cream cheese with (named added ingredients); Cream cheese spread; Cream cheese spread with (named added ingredients); Processed (named variety) cheese; Processed (named variety) cheese with (named added ingredients); Processed cheese food; Processed cheese food with (named added ingredients); Processed cheese spread; Processed cheese spread with (named added ingredients); Cold-pack (named variety) cheese; Cold-pack (named variety) cheese with (named added ingredients); Cold-pack cheese food; Cold-pack cheese food with (named added ingredients)	(1) 1,000 p.p.m. (2) 3,000 p.p.m. in accordance with the requirements of sections B.08.033, B.08.034, B.08.035, B.08.037, B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2 B.08.041.3, B.08.041.4, B.08.041.5, B.08.041.6, B.08.041.7, and B.08.041.08
30-4-96		(3) Cider; Wine; Honey wine (4) Unstandardized foods except unstandardized preparations of (a) meat and meat by-product (Division 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-products	(3) 500 p.p.m. (4) 1,000 p.p.m.

*(R) Minor correction

TABLE XI -- (continued)

PART IV

FOOD ADDITIVES THAT MAY BE USED AS CLASS IV PRESERVATIVES

Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
A.1	Ascorbic Acid	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
A.2	Ascorbyl Palmitate	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Unstandardized foods [except unstandardized preparations of (a) Meat and meat by-product (Divisions 14 and 21) (b) fish; and (c) poultry meat and poultry meat by-product] (3) Margarine	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) 0.02% of the fat content. If ascorbyl stearate is also used the total must not exceed 0.02% of the fat content
A.3	Ascorbyl Stearate	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Margarine	(1) Good Manufacturing Practice (2) 0.02% of the fat content. If ascorbyl palmitate is also used the total must not exceed 0.02% of the fat content.

17-11-77

25-8-76

17-11-77

*(R) Minor correction

TABLE XI

PART IV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
23-6-99	B.1	Butylated Hydroxyanisole (a mixture of 2-tertiary butyl-4-hydroxyanisole and 3-tertiary butyl-4-hydroxy-anisole	(1) Fats and oils, lard, shortening	(1) 0.02%. If butylated hydroxytoluene, propyl gallate or tertiary butyl hydroquinone is also used, the total must not exceed 0.02%.
15-5-68			(2) Dried breakfast cereals; Dehydrated potato products	(2) 0.005%. If butylated hydroxytoluene or propyl gallate is also used the total must not exceed 0.005%.
			(3) Chewing Gum	(3) 0.02%. If butylated hydroxytoluene or propyl gallate is also used the total must not exceed 0.02%.
			(4) Essential oils; Citrus oil flavours; Dry flavours	(4) 0.125%. If butylated hydroxytoluene or propyl gallate is also used the total must not exceed 0.125%.
			(5) Citrus oils	(5) 0.5%. If butylated hydroxytoluene or propyl gallate is also used the total must not exceed 0.5%.
			(6) Partially defatted pork fatty tissue; Partially defatted beef fatty tissue	(6) 0.0065%. If butylated hydroxytoluene is also used the total must not exceed 0.0065%.
			(7) Vitamin A liquids for addition to food	(7) 5 mg/1,000,000 International Units.
			(8) Dry beverage mixes; Dry dessert and confection mixes	(8) 0.009%
			(9) Active dry yeast	(9) 0.1%
28-4-77			(10) Other unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21) (b) fish; and (c) poultry meat and poultry meat by-product]	(10) 0.02% of the fat or the oil content of the food. If butylated hydroxytoluene or propyl gallate is also used the total must not exceed 0.02% of the fat or the oil content of the food
17-11-77			(11) Dry Vitamin D preparations for addition to food	(11) 10 mg/1,000,000 International Units
			(12) Margarine	(12) 0.01% of the fat content. If butylated hydroxytoluene or propyl gallate or both are also used the total must not exceed 0.01% of the fat content
12-11-81			(13) Dried cooked poultry meat	(13) 0.015% of the fat content. If propyl gallate or citric acid or both are also used, the total must not exceed 0.015% of the fat content

*(R) Minor correction

TABLE XI

PART IV -- (continued)

	Item No.	*Column I* Additive	*Column II* Permitted in or Upon	*Column III* Maximum Level of Use
23-6-99	B.2	Butylated Hydroxytoluene (3,5-ditertiary butyl-4-hydroxy-toluene)	(1) Fats and oils, lard, shortening	(1) 0.02%. If butylated hydroxyanisole, propyl gallate or tertiary butyl hydroquinone is also used, the total must not exceed 0.02%.
15-5-68			(2) Dried breakfast cereals; Dehydrated potato products	(2) 0.005%. If butylated hydroxy-anisole or propyl gallate is also used the total must not exceed 0.005%.
			(3) Chewing gum	(3) 0.02%. If butylated hydroxy-anisole or propyl gallate is also used the total must not exceed 0.02%.
			(4) Essential oils; Citrus oil flavours; Dry flavours	(4) 0.125%. If butylated hydroxy-anisole or propyl gallate is also used the total must not exceed 0.125%.
			(5) Citrus oils	(5) 0.5%. If butylated hydroxy-anisole or propyl gallate is also used the total must not exceed 0.5%.
28-4-77			(6) Partially defatted pork fatty tissue; Partially defatted beef fatty tissue	(6) 0.0065%. If butylated hydroxy-anisole is also used the total must not exceed 0.0065%.
			(7) Vitamin A liquids for addition to food	(7) 5 mg/1,000,000 International Units.
			(8) Parboiled rice	(8) 0.0035%.
			(9) Other unstandardized foods [except unstandardized preparations of (a) meat and meat by-products (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(9) 0.02% of the fat or the oil content of the food. If butylated hydroxyanisole or propyl gallate is also used the total must not exceed 0.02% of the fat or the oil content of the food.
28-4-77			(10) Dry Vitamin D preparations for addition to food	(10) 10 mg/1,000,000 International Units.
17-11-77			(11) Margarine	(11) 0.01% of the fat content. If butylated hydroxyanisole or propyl gallate or both are also used the total must not exceed 0.01% of the fat content.

*(R) Minor correction

TABLE XI

PART IV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
15-5-68 12-11-81	C.1	Citric Acid	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product] (3) Dried cooked poultry meat	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) 0.015% of the fat content. If butylated hydroxyanisole or propyl gallate or both are also used, the total must not exceed 0.015% of the fat content.
1-5-03	C.1.1	L-Cysteine	Nutritional supplements set out in section B.24.201	Good Manufacturing Practice
30-4-92	C.2	L-Cysteine Hydro-chloride	Sulphite replacement formulations for prepared fruits and vegetables	Good Manufacturing Practice
	G.1	Gum Guaiacum	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
	L.1	Lecithin	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(1) Good Manufacturing Practice (2) Good Manufacturing Practice

TABLE XI

PART IV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
L.2	Lecithin Citrate	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21) (b) fish; and (c) poultry meat and poultry meat by-product]	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
M.1	Mono-glyceride Citrate	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21) (b) fish; and (c) poultry meat and poultry meat by-product] (3) Margarine	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) 0.01% of the fat content. If monoisopropyl citrate or stearyl citrate or both are also used the total must not exceed 0.01% of the fat content
M.2	Mono-isopropyl Citrate	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21) (b) fish; and (c) poultry meat and poultry meat by-product] (3) Margarine	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) 0.01% of the fat content. If monoglyceride citrate or stearyl citrate or both are also used, the total must not exceed 0.01% of the fat content

17-11-77

15-5-68

17-11-77

*(R) Minor correction

TABLE XI

PART IV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
23-6-99	P.1	Propyl Gallate	(1) Fats and oils, lard, shortening	(1) 0.02%. If butylated hydroxyanisole, butylated hydroxytoluene or tertiary butyl hydroquinone is also used, the total must not exceed 0.02%.
			(2) Dried Breakfast cereals; Dehydrated potato products	(2) 0.005%. If butylated hydroxyanisole or butylated hydroxytoluene is also used, the total must not exceed 0.005%.
			(3) Chewing gum	(3) 0.02%. If butylated hydroxyanisole or butylated hydroxytoluene is also used, the total must not exceed 0.02%.
			(4) Essential oils; Dry flavours	(4) 0.125%. If butylated hydroxyanisole or butylated hydroxytoluene is also used, the total must not exceed 0.125%.
			(5) Citrus oils	(5) 0.5%. If butylated hydroxyanisole or butylated hydroxytoluene is also used, the total must not exceed 0.5%.
17-11-77			(6) Other unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(6) 0.02% of the fat or the oil content of the food. If butylated hydroxyanisole or butylated hydroxytoluene is also used, the total must not exceed 0.02% of the fat or the oil content of the food.
			(7) Margarine	(7) 0.01% of the fat content. If butylated hydroxyanisole or butylated hydroxytoluene or both are also used, the total must not exceed 0.01% of the fat content.
12-11-81			(8) Dried cooked poultry meat	(8) 0.015% of the fat content. If butylated hydroxyanisole or citric acid or both are also used, the total must not exceed 0.015% of the fat content.

*(R) Minor correction

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
T.1	Tartaric Acid	(1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening (2) Unstandardized foods [except unstandardized preparations of (a) meat and meat by-product (Division 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
T.1A	Tertiary Butyl Hydro-quinone	Fats and oils, lard, shortening	0.02%. If butylated hydroxyanisole, butylated hydroxytoluene or propylgallate is also used, the total must not exceed 0.02%.
T.2	Tocopherols (alpha-tocopherol; tocopherols concentrate, mixed)	(1) Fat and oils; Lard, Monoglycerides and diglycerides; Shortening (2) Unstandardized foods [except unstantandardized preparations of (a) meat and meat by-product (Divisions 14 and 21); (b) fish; and (c) poultry meat and poultry meat by-product]	(1) Good Manufacturing Practice (2) Good Manufacturing Practice

15-5-68

23-6-99

28-4-77

TABLE XII

FOOD ADDITIVES THAT MAY BE USED AS SEQUESTERING AGENTS

Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
A.1	Ammonium Citrate, dibasic	Unstandardized foods	Good Manufacturing Practice
A.2	Ammonium Citrate, monobasic	Unstandardized foods	Good Manufacturing Practice
C.1	Calcium Citrate	Unstandardized foods	Good Manufacturing Practice
C.2	Calcium Disodium Ethylene-diamine-tetraacetate	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout	(1) 25 p.p.m. calculated as the anhydrous form
		(2) French dressing; Mayonnaise; Salad dressing; Unstandardized dressings and sauces	(2) 75 p.p.m. calculated as the anhydrous form
		(3) Potato salad; Sandwich spread	(3) 100 p.p.m. calculated as the anhydrous form
		(4) Canned shrimp; Canned tuna	(4) 250 p.p.m. calculated as the anhydrous form
		(5) Canned crabmeat; Canned lobster; Canned salmon	(5) 275 p.p.m. calculated as the anhydrous form
		(6) Margarine	(6) 75 p.p.m. calculated as the anhydrous form
		(7) Canned clams	(7) 340 p.p.m. calculated as the anhydrous form
		(8) Canned ripe lima beans (butter beans); Canned pinto beans	(8) 130 p.p.m. calculated as the anhydrous form and in accordance with the requirements of subparagraph B.11.002(d)(vi)
		(9) Canned snails; Canned sea snails	(9) 300 p.p.m. calculated as the anhydrous form
		(10) Canned fava beans	(10) 365 p.p.m. calculated as the anhydrous form and in accordance with the requirements of subparagraph B.11.002(d)(vi.1)
		(11) Soft drinks; Ready-to-drink teas	(11) 33 p.p.m. calculated as the anhydrous form
		(12) Pasteurized *sous-vide* potatoes	(12) 100 p.p.m., singly or in combination with disodium EDTA, calculated as anhydrous disodium EDTA
C.3	Calcium Disodium EDTA	Same foods as listed for Calcium Disodium Ethylenediaminetetra-acetate	Same levels as prescribed for Calcium Disodium Ethylenediaminetetraacetate
C.4	Calcium Phosphate, monobasic	(1) Ice cream mix; ice milk mix; Sherbet	(1) Good Manufacturing Practice
		(2) Unstandardized dairy products	(2) Good Manufacturing Practice
C.5	Calcium Phosphate, tribasic	Ice cream mix; Ice milk mix	Good Manufacturing Practice

19-12-96

25-10-05

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
C.6	Calcium Phytate	Glazed fruit	Good Manufacturing Practice
C.7 15-5-68 9-12-97	Citric Acid	(1) Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product (2) Unstandardized foods (3) Frozen fish fillets; frozen minced fish; frozen comminuted fish	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) 0.1%
D.1 31-1-66 13-9-79 26-6-80 25-10-05	Disodium Ethylene-diamine-tetraacetate	(1) Dressing and sauces (2) Sandwich spread (3) Canned red kidney beans; Canned chick peas (garbanzo beans); Canned black-eye peas (4) Dried banana products (5) Aqueous suspensions of colour lake preparations for use in coating confectionery tablets (6) Pasteurized *sous-vide* potatoes	(1) 70 p.p.m. (2) 90 p.p.m. (3) 150 p.p.m. in accordance with the requirements of subparagraph B.11.002(d)(vii) (4) 265 p.p.m. (5) 1% of the colour preparation (6) 100 p.p.m., singly or in combination with calcium disodium EDTA, calculated as anhydrous disodium EDTA
D.2	Disodium EDTA	Same foods as listed for Disodium Ethylenediaminetetraacetate	Same levels as prescribed for Disodium Ethylenediaminetetraacetate
G.1	Glycine	Mono- and diglycerides	0.02%
P.1	Phosphoric Acid	Mono- and diglycerides	0.02%
P.2 24-3-94	Potassium Phosphate, monobasic	(1) Ice cream mix; Ice milk mix; Sherbet (2) Unstandardized foods (3) Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) 0.5% total added phosphate, calculated as sodium phosphate, dibasic
P.3 24-3-94	Potassium Pyro-phosphate, tetrabasic	(1) Meat tenderizers (2) Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product	(1) Good Manufacturing Practice (2) 0.5% total added phosphate, calculated as sodium phosphate, dibasic
P.4 24-3-94	Potassium Phosphate, dibasic	Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product	0.5% total added phosphate, calculated as sodium phosphate, dibasic

TABLE XII -- (continued)

	Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
25-10-05 26-2-76 10-6-82 24-3-94	S.1	Sodium Acid Pyro-phosphate	(1) Canned seafoods (2) Ice cream mix; Ice milk mix (3) Injection or cover solution for the curing of poultry or poultry meat (4) Pumping pickle for the curing of pork, beef and lamb cuts (5) Unstandardized foods (6) Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product	(1) Used singly or in combination with sodium hexametaphosphate or sodium tripolyphosphate, or both, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic (2) Good Manufacturing Practice (3) Good Manufacturing Practice, and in accordance with B.22.021(e) (4) Good Manufacturing Practice, and in accordance with B.14.009(f) and B.14.031(h) (5) Good Manufacturing Practice (6) 0.5% total added phosphate, calculated as sodium phosphate, dibasic
15-5-68	S.2	Sodium Citrate	(1) Ice cream mix, Ice milk mix; Sherbet; Pumping pickle; Cover pickle and Dry cure employed in the curing of preserved meat or preserved meat by-product (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
25-10-05 26-2-76 10-6-82 24-3-94	S.3	Sodium Hexameta-phosphate	(1) Canned seafoods (2) Ice cream mix; Ice milk mix (3) Injection or cover solution for the curing of poultry or poultry meat (4) Pumping pickle for the curing of pork, beef and lamb cuts (5) Unstandardized foods (6) Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product	(1) Used singly or in combination with sodium acid pyrophosphate or sodium tripolyphosphate, or both, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic (2) Good Manufacturing Practice (3) Good Manufacturing Practice, and in accordance with B.22.021(e) (4) Good Manufacturing Practice, and in accordance with B.14.009(f) and B.14.031(h) (5) Good Manufacturing Practice (6) 0.5% total added phosphate, calculated as sodium phosphate, dibasic
26-2-76 10-6-82 24-3-94	S.4	Sodium Phosphate, dibasic	(1) Ice cream mix, Ice milk mix; Sherbet (2) Injection or cover solution for the curing of poultry or poultry meat (3) Pumping pickle for the curing of pork, beef and lamb cuts (4) Unstandardized foods (5) Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product	(1) Good Manufacturing Practice (2) Good Manufacturing Practice, and in accordance with B.22.021(e) (3) Good Manufacturing Practice, and in accordance with B.14.009(f) and B.14.031(h) (4) Good Manufacturing Practice (5) 0.5% total added phosphate, calculated as sodium phosphate, dibasic

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
10-6-82 26-2-76 24-3-94	S.5	Sodium Phosphate, monobasic	(1) Ice cream mix; Ice milk mix; Sherbet (2) Injection or cover solution for the curing of poultry or poultry meat (3) Pumping pickle for the curing of pork, beef and lamb cuts (4) Unstandardized foods (5) Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product	(1) Good Manufacturing Practice (2) Good Manufacturing Practice, and in accordance with B.22.021(e) (3) Good Manufacturing Practice, and in accordance with B.14.009(f) and B.14.031(h) (4) Good Manufacturing Practice (5) 0.5% total added phosphate, calculated as sodium phosphate, dibasic
26-2-76 10-6-82 24-3-94	S.6	Sodium Pyro-phosphate, tetrabasic	(1) Ice cream mix; Ice milk mix; Sherbet (2) Meat tenderizers (3) Injection or cover solution for the curing of poultry or poultry meat (4) Pumping pickle for the curing of pork, beef and lamb cuts (5) Unstandardized foods (6) Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice, and in accordance with B.22.021(e) (4) Good Manufacturing Practice, and in accordance with B.14.009(f) and B.14.031(h) (5) Good Manufacturing Practice (6) 0.5% total added phosphate, calculated as sodium phosphate, dibasic
26-2-76 10-6-82 24-3-94 25-10-05	S.7	Sodium Tripoly-phosphate	(1) Injection or cover solution for the curing of poultry or poultry meat (2) Meat tenderizers (3) Pumping pickle for the curing of pork, beef and lamb cuts (4) Unstandardized foods (5) Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product (6) Canned seafoods	(1) Good Manufacturing Practice, and in accordance with B.22.021(e) (2) Good Manufacturing Practice (3) Good Manufacturing Practice, and in accordance with B.14.009(f) and B.14.031(h) (4) Good Manufacturing Practice (5) 0.5% total added phosphate, calculated as sodium phosphate, dibasic (6) Used singly or in combination with sodium acid pyrophosphate or sodium hexametaphosphate, or both, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic
17-11-77	S.8	Stearyl Citrate	Margarine	0.01% of the fat content. If mono-glyceride citrate or monoisopropyl citrate or both are also used, the total must not exceed 0.01% of the fat content

TABLE XIII

FOOD ADDITIVES THAT MAY BE USED AS STARCH MODIFYING AGENTS

Item No.	*Column I* *Additive*	*Column II* *Permitted in or Upon*	*Column III* *Maximum Level of Use*
A.1	Acetic Anhydride	Starch	Good Manufacturing Practice
A.2	Adipic Acid	Starch	Good Manufacturing Practice
A.3	Aluminum Sulphate	Starch	Good Manufacturing Practice
E.1	Epichlorohydrin	Starch	Good Manufacturing Practice
H.1	Hydrochloric Acid	Starch	Good Manufacturing Practice
H.2	Hydrogen Peroxide	Starch	Good Manufacturing Practice
M.1	Magnesium Sulphate	Starch	0.4%
N.1	Nitric Acid	Starch	Good Manufacturing Practice
O.1	Octenyl Succinic Anhydride	Starch	Good Manufacturing Practice
P.1	Peracetic Acid	Starch	Good Manufacturing Practice
P.2	Phosphorus Oxychloride	Starch	Good Manufacturing Practice
P.3	Potassium Permanganate	Starch	50 p.p.m. of Manganese Sulphate calculated as Manganese
P.4	Propylene Oxide	Starch	25%
S.1	Sodium Acetate	Starch	Good Manufacturing Practice
S.2	Sodium Bicarbonate	Starch	Good Manufacturing Practice
S.3	Sodium Carbonate	Starch	Good Manufacturing Practice
S.4	Sodium Chlorite	Starch	Good Manufacturing Practice
S.5	Sodium Hydroxide	Starch	Good Manufacturing Practice

17-12-69

*(R) Minor correction

TABLE XIII -- (concluded)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
S.6	Sodium Hypochlorite	Starch	Good Manufacturing Practice
S.7	Sodium Trimetaphosphate	Starch	400 p.p.m. calculated as Phosphorous
S.7A	Sodium Tripolyphosphate	Starch	Total residual phosphate not to exceed 0.4% (calculated as Phosphorus)
S.8	Succinic Anhydride	Starch	Good Manufacturing Practice
S.9	Sulphuric Acid	Starch	Good Manufacturing Practice

24-8-72

TABLE XIV

FOOD ADDITIVES THAT MAY BE USED AS YEAST FOODS

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
A.1	Ammonium Chloride	(1) Flour; Whole wheat flour (2) Bread (3) Unstandardized foods	(1) 2,000 p.p.m. of the flour (2) 2,500 p.p.m. of the flour For combinations see Section B.13.021(m) (3) Good Manufacturing Practice
A.2	Ammonium Phosphate, dibasic	(1) Bread (2) Cider; Honey wine; Wine (3) Unstandardized bakery foods	(1) 2,500 p.p.m. of the flour For combinations see Section B.13.021(m) (2) Good Manufacturing Practice (3) Good Manufacturing Practice
A.3	Ammonium Phosphate, monobasic	(1) Bread (2) Ale; Beer; Cider; Honey wine; Light beer; Malt liquor; Porter; Stout; Wine (3) Unstandardized bakery foods	(1) 2,500 p.p.m. of the flour For combinations see Section B.13.021(m) (2) Good Manufacturing Practice (3) Good Manufacturing Practice
A.4	Ammonium Sulphate	(1) Bread (2) Cider; Honey wine; Wine (3) Unstandardized bakery foods	(1) 2,500 p.p.m. of the flour For combinations see Section B.13.021(m) (2) Good Manufacturing Practice (3) Good Manufacturing Practice
C.1	Calcium Carbonate	(1) Bread (2) Unstandardized bakery foods	(1) 2,500 p.p.m. of the flour For combinations see Section B.13.021(m) (2) Good Manufacturing Practice
C.2	Calcium Chloride	Unstandardized bakery foods	Good Manufacturing Practice
C.3	Calcium Citrate	Unstandardized bakery foods	Good Manufacturing Practice
C.4	Calcium Lactate	(1) Bread (2) Unstandardized bakery foods	(1) 2,500 p.p.m. of the flour For combinations see Section B.13.021(m) (2) Good Manufacturing Practice
C.5	Calcium Phosphate, dibasic	(1) Bread (2) Unstandardized bakery foods	(1) 2,500 p.p.m. of flour For combinations See Section B.13.021(m) (2) Good Manufacturing Practice
C.6	Calcium Phosphate, Monobasic	(1) Bread (2) Flour (3) Unstandardized bakery foods	(1) 7,500 p.p.m. of flour For combinations see Section B.13.021(m) (2) 7,500 p.p.m. of flour (3) Good Manufacturing Practice

25-8-76

25-8-76

25-8-76

10-3-70

*(R) Minor correction

TABLE XIV -- (concluded)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
	C.7	Calcium Phosphate, tribasic	Unstandardized bakery foods	Good Manufacturing Practice
23-11-67	C.8	Calcium Sulphate	(1) Bread (2) Unstandardized foods	(1) 5,000 p.p.m. of flour (2) Good Manufacturing Practice
13-6-95	F.1	Ferrous Sulphate	Bacterial cultures	Good Manufacturing Practice
16-11-71	M.1	Manganese Sulphate	Ale; Beer; Light beer; Malt liquor; Porter; Stout	Good Manufacturing Practice
16-11-71	P.1	Phosphoric Acid	Ale; Beer; Light beer; Malt liquor; Porter; Stout	Good Manufacturing Practice
16-11-71	P.2	Potassium Chloride	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout (2) Unstandardized bakery foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
25-8-76	P.4	Potassium Phosphate, dibasic	(1) Ale; Beer; Cider; Honey wine; Light beer; Malt liquor; Porter; Stout; Wine (2) Unstandardized bakery foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice
25-7-76	P.5	Potassium Phosphate, monobasic	Ale; beer; Cider; Honey wine; Light beer; Malt liquor; Porter; Stout; Wine	Good Manufacturing Practice
	S.1	Sodium sulphate	Unstandardized bakery foods	Good Manufacturing Practice
18-12-86	U.1	Revoked by P.C. 1986-2842 of December 18, 1986		
13-6-95	Z.1	Zinc Sulphate	(1) Ale; Beer; Light beer; Malt liquor; Porter; Stout (2) Bacterial cultures	(1) Good Manufacturing Practice (2) Good Manufacturing Practice

*(R) Minor correction

TABLE XV

FOOD ADDITIVES THAT MAY BE USED AS CARRIER OR EXTRACTION SOLVENTS

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Residues	Column IV Maximum Level of Use
1.	Acetone	(1) Spice extracts; Natural extractives (2) Meat and Egg Marking Inks	(1) 30 p.p.m.	(2) Good Manufacturing Practice
2.	Benzyl Alcohol	(1) (naming the flavour) Flavour (Division 10) (2) Unstandardized flavouring preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice
3.	1,3-Butylene Glycol	(1) (naming the flavour) Flavour (Division 10) (2) Unstandardized flavouring preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice
3.1	Carbon Dioxide	(1) Green coffee beans and tea leaves for decaffeination purposes (2) Spice extracts; Natural extractives; (naming the flavour) Flavour (Division 10); Hop extract in accordance with subparagraph B.02.130(b)(v) and paragraph B.02.133(b); Pre-isomerized hop extract in accordance with subparagraph B.02.134(1)(a)(ii) (3) Egg products (4) Cocoa powder		(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice
4.	Castor Oil	Oil-soluble annatto; Annatto butter colour; Annatto margarine colour		Good Manufacturing Practice
5.	Ethyl Acetate	(1) Spice extracts; Natural extractives; (naming the flavour) Flavour (Division 10) (2) Unstandardized flavouring preparations (3) Green coffee beans for decaffeination purposes (4) Tea leaves for decaffeination purposes	(3) 10 p.p.m. in both roasted and decaffeinated soluble (instant) coffee (4) 50 p.p.m.	(1) Good Manufacturing Practice (2) Good Manufacturing Practice

1-4-82

4-12-86

1-11-94

14-5-96

7-10-96

23-1-75

2-12-82

27-9-90

*(R) Minor correction

TABLE XV -- (continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Residue	Column IV Maximum Level of Use
6.	Ethyl Alcohol (Ethanol)	(1) Spice extracts; Natural extractives; (naming the flavour) Flavour (Division 10) (2) Unstandardized flavouring preparations (3) Colour mixtures and preparations (Division 6) (4) Meat and Egg Marking Inks (5) Food additive preparations (6) Hop extract in accordance with subparagraph B.02.130(b)(v) and paragraph B.02.133(b); Pre-isomerized hop extract in accordance with subparagraph B.02.134(1)(a)(iii)		(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice (6) Good Manufacturing Practice
6.A	Ethyl alcohol denatured with methanol	Vegetable oil seed meals	10 p.p.m. methanol	
7.	Revoked by P.C. 1982-1091 of April 8, 1982			
8.	Glycerol (Glycerin)	(1) (naming the flavour) Extract; (naming the flavour) Essence; (naming the flavour) Flavour (Division 10) (2) Unstandardized flavouring preparations (3) Colour mixtures and preparations (Division 6) (4) Food additive preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice
9.	Glyceryl diacetate	(1) (naming the flavour) Flavour (Division 10) (2) Unstandardized flavouring preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice
10.	Glyceryl triacetate (Triacetin)	(1) (naming the flavour) Flavour (Division 10) (2) Unstandardized flavouring preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice

1-4-82
10-11-76
1-11-94
27-4-78
23-1-75
10-11-76

*(R) Minor correction

TABLE XV -- (continued)

	Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Residue	Column IV Maximum Level of Use
	11.	Glyceryl tributyrate (Tributyrin)	(1) (naming the flavour) Flavour (Division 10) (2) Unstandardized flavouring preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice
1-11-94	12.	Hexane	(1) Spice extracts; Natural extractives (2) Hop extract in accordance with sub-paragraph B.02.130(b)(v) and paragraph B.02.133(a) (3) Vegetable fats and oils (4) Vegetable oil seed meals (5) Pre-isomerized hop extract in accordance with subparagraph B.02.134(1)(a)(i) and subsection B.02.134(2)	(1) 25 p.p.m. (2) 2.2% (3) 10 p.p.m. (4) 10 p.p.m. (5) 1.5 p.p.m. per percent iso-alpha acid content of the pre-isomerized hop extract	
1-4-82	13.	Isopropyl alcohol (Isopro-panol)	(1) Spice extracts; Natural extractives (2) Fish protein (3) (naming the flavour)Flavour (Division 10) (4) Unstandardized flavouring preparations (5) Meat and Egg Marking Inks	(1) 50 p.p.m. (2) 0.15%	(3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice
1-11-94 1-4-82	14.	Methyl Alcohol (methanol)	(1) Spice extracts; Natural extractives (2) Hop extract in accordance with sub-paragraph B.02.130 (b)(v) and paragraph B.02.133(a) (3) Meat and Egg Marking Inks	(1) 50 p.p.m. (2) 0.15%	(3) Good Manufacturing Practice
7-10-82	14.1	Methyl ethyl ketone (2-Butanone)	(1) Spice extracts; Natural extractives	(1) 50 p.p.m.	

*(R) Minor correction

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Residue	Column IV Maximum Level of Use
10-8-77 1-11-94 12-7-84	15. Methylene Chloride (Dichloro-methane)	(1) Spice extracts; Natural extractives (2) Hop extract in accordance with sub-paragraph B.02.130(b)(v) and paragraph B.02.133(a) (3) Green coffee beans and Tea leaves for decaffeination purposes	(1) 30 p.p.m. (2) 2.2% in hop extract (3) 10 p.p.m. in decaffeinated roasted coffee, decaffeinated soluble (instant) coffee, decaffeinated tea leaves and decaffeinated instant tea	
23-1-75 10-11-76	16. Monogly-cerides and diglycerides	(1) (naming the flavour) Flavour (Division 10) (2) Oil-soluble annatto; Annatto butter colour; Annatto margarine colour (3) Unstandardized flavouring preparations (4) Food Additive preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice
	17. Monogly-ceride citrate	(1) Spice extracts; Natural extractives (2) Unstandardized flavouring preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice
	18. 2-Nitro-propane	Vegetable oils	0.5 p.p.m.	

*(R) Minor correction

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Residue	Column IV Maximum Level of Use
19.	1,2-Propylene glycol (1,2-propanediol)	(1) (naming the flavour) Extract; (naming the flavour) Essence; (naming the flavour) Flavour (Division 10) (2) Oil-soluble annatto; Annatto butter colour; Annatto margarine colour (3) Unstandardized flavouring preparations (4) Colour mixtures and preparations (Division 6) (5) Food additive preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice
20.	Propylene glycol monoesters and diesters of fat-forming fatty acids	Oil-soluble annatto; Annatto butter colour; Annatto margarine colour		Good Manufacturing Practice
21.	Triethyl-citrate	(1) (naming the flavour) Flavour (Division 10) (2) Unstandardized flavouring preparations		(1) Good Manufacturing Practice (2) Good Manufacturing Practice
22.	Revoked by P.C. 1977-204 of February 3, 1977			

10-11-76

23-1-75

3-2-77

*(R) Minor correction

Salt

B.17.001.(1) [S]. **Salt**, other than crude rock salt, shall be crystalline sodium chloride and may contain:

(a) one or more of the following anti-caking agents,

4-12-86 (i) calcium aluminum silicate, calcium phosphate tribasic, calcium silicate, calcium stearate, magnesium carbonate, magnesium silicate, magnesium stearate, silicon dioxide and sodium aluminum silicate, the total amount not to exceed 1 per cent and, in the case of fine grained salt, the total amount not to exceed 2 per cent,

(ii) propylene glycol in an amount not exceeding 0.035 per cent, and

(iii) sodium ferrocyanide decahydrate in an amount not exceeding 13 parts per million calculated as anhydrous sodium ferrocyanide;

(b) not more than

(i) 1.4 per cent, singly or in combination, of calcium sulphate or potassium chloride,

13-9-79 (ii) 13 parts per million sodium ferrocyanide when added as sodium ferrocyanide decahydrate in the production of dendritic crystals of salt,

(iii) 10 parts per million of polyoxyethylene (20) sorbitan monooleate when used in the production of coarse crystal salt,

(iv) 15 parts per million of sodium alginate when used in the production of coarse crystal salt, and

(v) 0.1 per cent other ingredients; and

(c) notwithstanding paragraphs (a) and (b), the total level of sodium ferrocyanide decahydrate, whether added as an anti-caking agent or as an adjuvant in the production of dendritic salt, shall not exceed 13 parts per million, calculated as anhydrous sodium ferrocyanide.

19-3-97 (2) Repealed by P.C. 1997-381 of March 19, 1997.

13-9-79 **B.17.002.** Repealed by P.C. 1979-2453 of September 13, 1979.

13-5-75 **B.17.003.** Notwithstanding section B.17.001, salt for table or general household use shall contain 0.01 per cent potassium iodide, with or without dextrose, sodium thiosulphate or sodium bicarbonate as a stabilizer of the iodide and the presence of iodide shall be shown on the principal display panel.

Sweetening Agents

B.18.001. [S]. Sugar

(a) shall be the food chemically known as sucrose; and
(b) shall contain not less than 99.8 per cent sucrose.

B.18.002. [S]. Liquid Sugar shall be the food obtained by dissolving sugar in water.

31-1-66 **B.18.003. [S]. Invert Sugar** shall be the food obtained by the partial or complete hydrolysis of sugar.

B.18.004. [S]. Liquid Invert Sugar shall be the food consisting of a solution of invert sugar in water.

B.18.005. No person shall sell liquid sugar or liquid invert sugar unless the label carries a statement of the percentage of sugar or invert sugar contained therein.

B.18.006. [S]. Icing Sugar

(a) shall be powdered sugar; and
9-8-67 (b) may contain
(i) food colour, and
(ii) either not more than 5 per cent starch or an anti-caking agent.

B.18.007. [S]. Brown Sugar, Yellow Sugar or **Golden Sugar**

(a) shall be the food obtained from the syrups originating in the sugar refining process;
(b) may contain not more than
(i) 4.5 per cent moisture, and
(ii) 3.5 per cent sulphated ash; and

(c) shall not contain less than 90 per cent sugar and invert sugar.

31-1-66

B.18.008. [S]. Refined Sugar Syrup, Refiners' Syrup or **Golden Syrup**

(a) shall be the food made from syrup originating in the sugar refining process;
(b) may be hydrolyzed; and
(c) may not contain more than
(i) 35 per cent moisture, and
(ii) 2.5 per cent sulphated ash.

B.18.009. [S]. Fancy Molasses

(a) shall be the syrupy food obtained by the evaporation and partial inversion of the clarified or unclarified sugar cane juice from which sugar has not been previously extracted;
28-9-67 (b) may contain sulphurous acid or its salts;
(c) shall not contain more than
(i) 25 per cent moisture, and
(ii) 3 per cent sulphated ash.

B.18.010. [S]. Table Molasses

(a) shall be the liquid food obtained in the process of manufacturing raw or refined sugar;
(b) may contain sulphurous acid or its salts;
31-1-66 (c) shall not contain more than
(i) 25 per cent moisture, and
(ii) 3 per cent sulphated ash.

B.18.011. [S]. Refiners' Molasses, Blackstrap Molasses or **Cooking Molasses**

(a) shall be the residual liquid food obtained in the process of manufacturing raw or refined sugar;
31-1-66 (b) may contain sulphurous acid or its salts;
(c) shall not contain more than
(i) 25 per cent moisture, and
(ii) 12 per cent sulphated ash.

12-4-84 **B.18.015. [S].** (1) Dextrose Anhydrous, for the purpose of Part B of these Regulations

(a) shall be the food chemically known as dextrose;
(b) shall contain not less than 99.5 per cent **D**-glucose on a dry basis;
(c) shall contain not more than 0.25 per cent sulphated ash on a dry basis;
(d) shall contain not less than 98 per cent total solids; and
(e) may contain sulphurous acid or its salts.

(2) Dextrose Monohydrate, for the purpose of Part B of these Regulations

(a) shall be the food chemically known as dextrose;
(b) shall contain not less than 99.5 per cent D-glucose on a dry basis;
(c) shall contain not more than 0.25 per cent sulphated ash on a dry basis;
(d) shall contain not less than 90 per cent total solids; and
(e) may contain sulphurous acid or its salts.

B.18.016. [S]. Glucose or **Glucose Syrup**

27-4-78 (a) shall be the purified concentrated solution of nutritive saccharides obtained from the incomplete hydrolysis, by means of acid or enzymes, of starch or of a starch-containing substance;
(b) shall have a total solids content of not less than 70 per cent;
(c) shall have a sulphated ash content of not more than 1.0 per cent on a dry basis;
26-2-76 (d) shall have a reducing sugar content (dextrose equivalent) of not less than 20 per cent expressed as **D**-glucose on a dry basis; and
(e) may contain sulphurous acid or its salts.

B.18.017. [S]. Glucose Solids or **Dried Glucose Syrup**

(a) shall be glucose or glucose syrup from which the water has been partially removed;
(b) shall have a total solids content of not less than 93 per cent;
(c) shall have a sulphated ash content of not more than 1.0 per cent on a dry basis;
(d) shall have a reducing sugar content (dextrose equivalent) of not less than 20 per cent expressed as **D**-glucose, on a dry basis; and
(e) may contain sulphurous acid or its salts.

B.18.018. [S]. (Naming the source of the glucose) Syrup

(a) shall be glucose;
(b) may contain
(i) a sweetening agent,
31-6-66 (ii) a flavouring preparation,
(iii) sorbic acid,
(iv) sulphurous acid or its salts,
13-1-94 (v) salt, and
(vi) water; and

(c) shall not contain more than
(i) 35 per cent moisture; and
(ii) 3 per cent ash.

B.18.019. [S]. Lactose

(a) shall be the carbohydrate normally obtained from whey and may
  (i) be anhydrous,
  (ii) contain one molecule of water of crystallization, or
5-11-74 (iii) be a mixture of both (i) and (ii);
(b) shall not contain less than 99.0% anhydrous lactose on a moisture free basis;
(c) shall not contain more than 0.3% sulphated ash on a moisture free basis;
(d) shall have a weight loss of not more than 6.0% on drying; and
(e) shall have, in a 10% solution, a pH of not less than 4.5 and not more than 7.0.

Honey

B.18.025. [S]. Honey shall be the food produced by honey bees and derived from

(a) the nectar of blossoms,
(b) secretions of living plants, or
(c) secretions on living plants,

and shall have

(d) a fluid, viscous or partly or wholly crystallized consistency;
(e) a diastase activity, determined after processing and blending, as represented by a diastase figure on the Gothe scale of not less than 8 where the hydroxy-methyl-furfural content is not more than 0.004 per cent; or
(f) a diastase activity, determined after processing and blending, as represented by a diastase figure on the Gothe scale of not less than 3 where the hydroxy-methyl-furfural content is not more than 0.0015 per cent.

B.18.026. (1) Subject to subsection (2), honey derived mainly from nectar of blossoms shall not contain

(a) less than 65 per cent apparent reducing sugar, calculated as invert sugar;
18-3-75 (b) more than 20 per cent moisture;
(c) more than 5 per cent apparent sucrose;
(d) more than 0.1 per cent water insoluble solids, except that pressed honey shall contain not more than 0.5 per cent water insoluble solids;
(e) more than 0.6 per cent ash; and
(f) more than 40 milliequivalents acid per 1000 grams.

(2) Honey derived mainly from the nectar of lavender, rubinia, alfalfa, or banksia menziesii shall meet the requirements of paragraphs (1)(a), (b) and (d) to (f) and shall contain not more than 10 per cent apparent sucrose.

B.18.027. Honey derived from secretions of living plants or from secretions on living plants shall not contain

(a) less than 60 per cent apparent reducing sugar, calculated as invert sugar;
(b) more than 20 per cent moisture;
(c) more than 10 per cent apparent sucrose;
(d) more than 0.1 per cent water insoluble solids, except that pressed honey shall contain not more than 0.5 per cent water insoluble solids;
(e) more than 1.0 per cent ash; and
(f) more than 40 milliequivalents acid per 1000 grams.

Vinegar

11-5-93 **B.19.001.** Vinegar shall be the liquid obtained by the acetous fermentation of an alcoholic liquid and shall contain not less than 4.1 per cent and not more than 12.3 per cent acetic acid.

13-5-75 **B.19.002.** The percentage of acetic acid by volume contained in any vinegar described in Division 19 shall be shown on the principal display panel followed by the words "acetic acid".

B.19.003. [S]. Wine Vinegar shall be vinegar made from wine and may contain caramel.

B.19.004. [S]. Spirit Vinegar, Alcohol Vinegar, White Vinegar or **Grain Vinegar** shall be vinegar made from diluted distilled alcohol.

3-9-64 **B.19.005. [S]. Malt Vinegar** shall be vinegar made from an infusion of malt undistilled prior to acetous fermentation, and may contain other cereals or caramel, shall be dextro-rotatory, and shall contain, in 100 millilitres measured at a temperature of 20°C, not less than

(a) 1.8 grams of solids; and
(b) 0.2 gram of ash.

B.19.006. [S]. Cider Vinegar or **Apple Vinegar** shall be vinegar made from the liquid expressed from whole apples, apple parts or apple culls and may contain caramel.

B.19.007. [S]. Blended Vinegar shall be a combination of two or more varieties of vinegar of which spirit vinegar shall contribute not more than 55 per cent of the total acetic acid.

B.19.008. No person shall name any of the varieties of vinegar forming a blended vinegar unless the label of such blended vinegar carries a complete list of all the varieties of vinegar present in descending order of proportionate content, based on acetic acid.

13-5-75 **B.19.009.** The maximum limits for the acetic acid content of a vinegar described in section B.19.001 do not apply to vinegar sold only for manufacturing use if the words "For Manufacturing Use Only" are shown on the principal display panel and upon all documents pertaining to such vinegar.

Tea

3-9-64 **B.20.001. [S]. Tea** shall be the dried leaves and buds of *Thea sinensis* (L.) Sims prepared by the usual trade processes.

B.20.002. [S]. Black Tea shall be black tea or a blend of two or more black teas and shall contain, on the dry basis, not less than 30 per cent water-soluble extractive, as determined by official method FO-37, Determination of Water-Soluble Extractive in Tea, October 15, 1981, and not less than four per cent and not more than seven per cent total ash.

5-8-82 **B.20.003.** The provisions of B.20.002 do not apply to original unblended black tea that contains, on the dry basis, not less than 25 per cent water-soluble extractive, as determined by official method FO-37, Determination of Water-Soluble Extractive in Tea, October 15, 1981, and not less than four per cent and not more than seven per cent total ash, and is packaged according to good commercial practice in the country of origin.

B.20.004. [S]. Green Tea shall contain, on the dry basis, not less than 33 per cent water-soluble extractive, as determined by official method FO-37, Determination of Water-Soluble Extractive in Tea, October 15, 1981, and not less than four per cent and not more than seven per cent total ash.

27-7-90 **B.20.005. [S]. Decaffeinated (indicating the type of tea)**

(a) shall be tea of the type indicated, from which caffeine has been removed and that, as a result of the removal, contains not more than 0.4 per cent caffeine; and

(b) may have been decaffeinated by means of extraction solvents set out in Table XV to Division 16.

Marine and Fresh Water Animal Products

B.21.001. The foods referred to in this Division are included in the term marine and fresh water animal products.

B.21.002. In this Division

3-9-64 "filler" means

(a) flour or meal prepared from grain or potato, but not from a legume;

5-8-82 (b) processed wheat flour containing not less than the equivalent of 80 per cent dextrose, as determined by official method FO-32, Determination of Fillers, Binders and Dextrose Equivalent, October 15, 1981;

(c) bread, biscuit or bakery products, but not those containing or made with a legume;

(d) milk powder, skim milk powder, buttermilk powder or whey powder; and

28-4-77 (e) starch;

"Marine and fresh water animal" includes

(a) fish;

25-3-65 (b) crustaceans, molluscs, other marine invertebrates,

(c) marine mammals, and

6-5-75 (d) frogs.

12-4-84 **B.21.003. [S].** Fish shall be the clean, dressed edible portion of fish, with or without salt or seasoning, and may

9-12-97 (a) in the case of frozen fillets, contain ascorbic acid or its sodium salt, citric acid, or erythorbic acid or its sodium salt, and

17-10-88 (i) sodium tripolyphosphate, sodium hexametaphosphate or a combination of sodium tripolyphosphate, sodium acid pyrophosphate and sodium pyrophosphate tetrabasic, or

(ii) a mixture of sodium hexametaphosphate and sodium carbonate;

17-7-75 (b) if frozen, have a glaze consisting of water, acetylated monoglycerides, calcium chloride, sodium alginate, sodium carboxymethyl cellulose, sodium phosphate (dibasic), corn syrup, dextrose, glucose, glucose solids, ascorbic acid or its sodium salt or erythorbic acid or its sodium salt; and

9-12-97 (c) if frozen minced, contain sodium tripolyphosphate, sodium hexametaphosphate, ascorbic acid or its sodium salt, citric acid, erythorbic acid or its sodium salt, or a combination of sodium tripolyphosphate, sodium acid pyrophosphate and sodium pyrophosphate tetrabasic.

14-2-91 **B.21.004. [S].** In this Division, meat shall be the clean, dressed flesh of crustaceans, molluscs, other marine invertebrates and marine mammals, whether minced or not, with or without salt or seasoning, and in the case of frozen lobster, frozen crab, frozen shrimp and frozen clams, may contain sodium tripolyphosphate or sodium hexametaphosphate or a combination of sodium hexametaphosphate and sodium carbonate or a combination of sodium tripolyphosphate, sodium acid pyrophosphate and sodium pyrophosphate tetrabasic.

16-9-70 **B.21.005.** Fish, except fish protein, and meat products or preparations thereof are adulterated if any of the following substances or any substance in one of the following classes is present therein or has been added thereto:

(a) mucous membranes, any organ or portion of the genital system, or any organ or portion of a marine or fresh water animal that is not commonly sold as an article of food;

(b) preservatives, other than those provided for in this Division, except

(i) sorbic acid or its salts in dried fish that has been smoked or salted, and in cold processed smoked and salted fish paste, and

23-11-67 (ii) benzoic acid or its salts, methyl-p-hydroxy benzoate and propyl-p-hydroxy benzoate in marinated or similar cold-processed, packaged fish and meat products; and

(c) food colour except as provided for in this Division.

31-1-66 **B.21.006. [S].** Prepared fish or prepared meat shall be the whole or comminuted food prepared from fresh or preserved fish or meat respectively, may be canned or cooked, and may,

(a) in the case of lobster paste and fish roe (caviar), contain food colour;

9-3-71 (b) in the case of canned shellfish, canned spring mackerel and frozen cooked shrimp, contain citric acid or lemon juice;

8-1-81 (c) in the case of fish paste, contain filler, fish binder, monoglycerides or mono and diglycerides;

(d) in the case of canned salmon, tuna, lobster, crab-meat and shrimp, contain calcium disodium ethylenediaminetetraacetate (calcium disodium EDTA) and aluminum sulphate;

13-5-75 (e) in the case of canned tuna, contain ascorbic acid;

25-10-05 (f) in the case of canned seafoods, contain sodium acid pyrophosphate, sodium hexametaphosphate or sodium tripolyphosphate, singly, or in combination, at a maximum level of total added phosphate not to exceed 0.5%, calculated as sodium phosphate, dibasic;

19-3-97 (g) contain liquid smoke flavour or liquid smoke flavour concentrate;

(h) contain edible oil, vegetable broth and tomato sauce or puree;

(i) contain a gelling agent if the principal display panel carries the word "jellied" as an integral part of the common name;

13-5-75 (j) contain salt;

1-11-94 (k) in the case of canned snails, canned sea snails and canned clams, contain calcium disodium ethylenediamine tetra-acetate;

(l) in the case of canned flaked tuna, contain sodium sulphite;

(m) in the case of lumpfish caviar, contain tragacanth gum;

25-5-93 (n) in the case of a blend of prepared fish and prepared meat that has the appearance and taste of the flesh of a marine or freshwater animal, contain filler, fish binder, whole egg, egg-white, egg-yolk, food colour, gelling or stabilizing agents, texture-modifying agents, natural and artificial flavouring preparations, pH-adjusting agents, sweetener and, in a proportion not exceeding two per cent of the blend, a legume;

9-10-86 (o) in the case of crustaceans, contain potassium bisulphite, potassium metabisulphite, sodium bisulphite, sodium dithionite, sodium metabisulphite, sodium sulphite or sulphurous acid;

6-4-89 (p) in the case of frozen crustaceans and molluscs, contain calcium oxide and sodium hydroxide;

9-12-97 (q) in the case of frozen pre-cooked battered or breaded fish products, contain citric acid at a level of use not exceeding 0.1 per cent; and

25-10-05 (r) in the case of canned clams, contain sodium erythorbate at a level of use not exceeding 350 parts per million.

25-3-65 **B.21.007. [S]. Fish binder** for use in or upon prepared fish or prepared meat shall be filler with any combination of salt, sugar, dextrose, glucose, spices and other seasonings.

3-9-64 **B.21.008.** No person shall sell filler or a fish binder represented for use in fish products either by label or in any advertisement unless the label carries adequate directions for use in accordance with the limits provided in section B.21.020.

10-11-76 **B.21.009.** Powdered hydrogenated cottonseed oil in an amount not greater than 0.25 per cent of the product may be applied as a release agent to the surface of marine and fresh water animal products.

Prepared Fish

3-9-64 **B.21.020.** No person shall sell prepared fish or prepared meat that contains more than

5-8-82 (a) that amount of filler, fish binder or other ingredients that is represented by four per cent reducing sugars, calculated as dextrose, as determined by official method FO-32, Determination of Fillers, Binders and Dextrose Equivalent, October 15, 1981; and

3-9-64 (b) 70 per cent moisture where such prepared fish contains filler.

23-11-67 **B.21.021. [S].** Preserved fish or preserved meat shall be cooked or uncooked fish or meat that is dried, salted, pickled, cured or smoked and may contain Class I Preservatives, dextrose, glucose, spices, sugar and vinegar, and

(a) dried fish that has been smoked or salted, and cold processed smoked and salted fish paste may contain sorbic acid or its salts;

(b) smoked fish may contain food colour;

1-10-68 (c) packaged fish and meat products that are marinated or otherwise cold-processed may contain sauderswood (sandalwood), benzoic acid or its salts, methyl-p-hydroxy benzoate and propyl-p-hydroxy benzoate; and

17-10-95 (d) salted anchovy, salted scad and salted shrimp may contain erythrosine in such amount as will result in the finished product containing not more than 125 parts per million of erythrosine.

B.21.022. Revoked by P.C. 1979-675 of March 8, 1979.

B.21.023. Revoked by P.C. 1979-675 of March 8, 1979.

3-9-64 **B.21.024.** Notwithstanding section B.21.020 lobster paste shall not contain more than 2 per cent filler or fish binder.

B.21.025. No person shall sell marine and fresh water animals, or marine and fresh water animal products, that are packed in a container that has been sealed to exclude air and that are smoked or to which liquid smoke flavour or liquid smoke flavour concentrate has been added, unless

(a) the container has been heat-processed after sealing at a temperature and for a time sufficient to destroy all spores of the species *Clostridium botulinum*;

16-8-94 (b) the contents of the container contain not less than nine per cent salt, as determined by official method FO-38, *Determination of Salt in Smoked Fish*, dated March 15, 1985;

(c) the contents of the container are customarily cooked before eating; or

(d) the contents of the container are frozen and the principal display panel of the label of the container carries the statement "Keep Frozen Prior to Use" in the same size type used for the common name of the contents of the container.

B.21.027. [S]. Fish Protein

(a) shall be the food prepared by

(i) extracting water, fat and other soluble components through the use of isopropyl alcohol from fresh whole edible fish of the order Clupeiformes, families Clupeidae and Osmeridae and the order Gadiformes, family Gadidae, or from trimmings resulting from the filleting of such fish when eviscerated, and

(ii) drying and grinding the protein concentrate resulting from the operation described in subparagraph (i);

(b) may contain a pH adjusting agent; and

(c) shall not contain

5-8-82 (i) less than 75 per cent protein, which protein shall be at least equivalent to casein in protein quality, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981,

19-3-97 (ii) and (iii) are repealed by P.C. 1997-378 of March 19, 1997.

Froglegs

5-8-82 **B.21.031.** No person shall sell fresh or frozen froglegs unless they are free from bacteria of the genus Salmonella, as determined by official method MFO-10, Microbiological Examination of Froglegs, November 30, 1981.

Poultry, Poultry Meat, their Preparations and Products

3-9-64 **B.22.001. [S]. Poultry** shall be any bird that is commonly used as food.

19-12-79 **B.22.002. [S].** Poultry meat shall be the clean, dressed flesh, including the heart and gizzard of eviscerated poultry that is healthy at the time of slaughter.

B.22.003. [S]. Poultry meat by-product shall be the clean parts of poultry other than poultry meat commonly used as food and includes liver and skin, but excludes the oesophagus, feet and head.

B.22.004. [S]. Giblets shall be the heart, liver and gizzard of poultry.

B.22.005. Poultry meat, poultry meat by-products or preparations thereof are adulterated if any of the following substances or any substance in the following classes is present therein or has been added thereto:

12-11-81

(a) any organ or portion of poultry that is not commonly sold as food;
(b) preservatives, other than those provided for in this DIVISION; and
(c) colour, other than caramel.

B.22.006. [S]. Prepared poultry meat or a **prepared poultry meat by-product** shall be any poultry meat or any poultry meat by-product, respectively, whether comminuted or not, to which has been added any ingredient permitted by these Regulations or that has been preserved, placed in a hermetically-sealed container or cooked, and may contain

24-3-94

(a) where a minimum total protein content or minimum meat protein requirement is prescribed in this Division, phosphate salts that do not when calculated as sodium phosphate, dibasic, exceed the maximum level provided therefor in Table XII to section B.16.100 and that are one or more of the following phosphate salts, namely,
    (i) sodium acid pyrophosphate,
    (ii) sodium hexametaphosphate,
    (iii) sodium phosphate, dibasic,
    (iv) sodium phosphate, monobasic,
    (v) sodium pyrophosphate, tetrabasic,
    (vi) sodium tripolyphosphate,
    (vii) potassium phosphate, monobasic,
    (viii) potassium phosphate, dibasic, and
    (ix) potassium pyrophosphate, tetrabasic; and
(b) in the case of dried, cooked poultry meat, a Class IV preservative.

13-8-86 **B.22.008.** In this Division, "filler" means any vegetable material (except tomato or beetroot), milk, egg, yeast, or any derivative or combination thereof that is acceptable as food.

4-3-63 **B.22.009.** No person shall sell

22-10-87

(a) any poultry intended for consumption as food if any preparation having oestrogenic activity has been administered to the poultry; or
(b) poultry meat or poultry meat by-product that contains any residues of exogenous oestrogenic substances.

10-11-76 **B.22.010.** Powdered hydrogenated cottonseed oil in an amount not greater than 0.25 per cent of the product may be applied as a release agent to the surface of poultry meat, poultry meat by-product, prepared poultry meat, prepared poultry meat by-product, extended poultry product and simulated poultry product.

24-3-94 **B.22.011. [S]. Solid cut poultry meat** shall be

(a) a whole cut of poultry meat; or
(b) a product consisting of pieces of poultry meat of which at least 80 per cent weigh at least 25 g each.

*(R) Minor correction

B.22.012. (1) No person shall sell solid cut poultry meat to which phosphate salts or water has been added unless

(a) that meat
  (i) where cooked, contains a meat protein content of not less than 12 per cent, and
  (ii) where uncooked, contains a meat protein content of not less than 10 per cent; and

(b) that meat contains, phosphate salts that do not when calculated as sodium phosphate, dibasic, exceed the maximum level provided therefor in Table XII to section B.16.100 and that are one or more of the following phosphate salts, namely,
  (i) sodium acid pyrophosphate,
  (ii) sodium hexametaphosphate,
  (iii) sodium phosphate, dibasic,
24-3-94 (iv) sodium phosphate, monobasic,
  (v) sodium pyrophosphate, tetrabasic,
  (vi) sodium tripolyphosphate,
  (vii) potassium phosphate, monobasic,
  (viii) potassium phosphate, dibasic, and
  (ix) potassium pyrophosphate, tetrabasic.

(2) A bone or a visible fat layer shall not be included in any calculation used to determine meat protein content for the purposes of paragraph (1)(a).

B.22.013. No person shall sell the whole or any part of a dressed poultry carcass that has been placed in a chilling tank containing fluids to which phosphate salts have been added.

Poultry Meat Stews

B.22.016. For the purposes of sections B.22.017 to B.22.019, "stew poultry meat" means cooked or uncooked poultry meat containing not more than 15 per cent fat, calculated on the weight of uncooked stew poultry meat.

16-11-78 **B.22.017. [S]. Vegetable Stew with (naming the poultry meat)**

(a) shall contain vegetables and the named poultry meat in the following amounts:
  (i) if uncooked, 12 per cent or more of the named stew poultry meat,
  (ii) if cooked, 6 per cent or more of the named stew poultry meat,
  (iii) 38 per cent or more vegetables; and

(b) may contain gravy, salt, seasoning and spices.

B.22.018. [S]. (naming the poultry meat) Stew

(a) shall contain vegetables and the named poultry meat in the following amounts:
  (i) if uncooked, 20 per cent or more of the named stew poultry meat,
16-11-78 (ii) if cooked, 10 per cent or more of the named stew poultry meat,
  (iii) 30 per cent or more vegetables; and

(b) may contain gravy, salt, seasoning and spices.

B.22.019. [S]. Specialty Poultry Meat Stew

(a) shall contain poultry meat and vegetables in the following amounts:
  (i) if uncooked, 25 per cent or more of stew poultry meat,
16-11-78 (ii) if cooked, 15 per cent or more of stew poultry meat,
  (iii) 30 per cent or more vegetables; and

(b) may contain gravy, salt, seasoning and spices.

Prepared Poultry Meats, Prepared Poultry Meat By-products

13-8-86 **B.22.020.** Revoked by P.C. 1986-1844 of August 13, 1986.

B.22.021. [S]. Preserved poultry meat or preserved poultry meat by-product shall be cooked or uncooked poultry meat or poultry meat by-product that is cured or smoked and may contain

(a) Class I preservatives;
16-8-94 (b) liquid smoke flavour, liquid smoke flavour concentrate or spices;
(c) sweetening agents;
(d) vinegar; and
10-6-82 (e) in the case of cured poultry or poultry meat prepared by means of injection or cover solution, disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate and sodium acid pyrophosphate, in such amount calculated as disodium phosphate, as will result in the finished product containing not more than 0.5 per cent added phosphate.

3-9-64 **B.22.022. [S].** Canned (naming the poultry) shall be prepared from poultry meat and may contain

(a) those bones or pieces of bones attached to the portion of the poultry meat that is being canned;
(b) broth;
(c) salt;
9-5-58 (d) seasoning;
(e) gelling agents; and
(f) small amounts of fat.

3-9-64 **B.22.023. [S].** Broth that is used in canned (naming the poultry) shall be the liquid in which the poultry meat has been cooked.

13-5-75 **B.22.024.** Where a gelling agent has been added to canned poultry, a statement to the effect that a gelling agent has been added shall be shown on the principal display panel or the word "jellied" shall be shown as an integral part of the common name of the food.

5-8-82 **B.22.025. [S]. Boneless (naming the poultry)** shall be canned poultry meat from which the bones and skin have been removed, shall contain not less than 50 per cent of the named poultry meat, as determined by official method FO-39, Determination of Meat in Boneless Poultry, October 15, 1981, and may contain broth having a specific gravity of not less than 1.000 at a temperature of 50°C.

B.22.026. No person shall sell poultry, poultry meat or poultry meat by-product that has been barbecued, roasted or broiled and is ready for consumption unless the cooked poultry, poultry meat or poultry meat by-product

28-4-77 (a) at all times
(i) has a temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher, or
(ii) has been stored at an ambient temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher, and

23-6-88 (b) carries on the principal display panel of the label a statement to the effect that the food must be stored at a temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher.

Poultry Product Extender

B.22.027. No person shall sell a poultry product extender unless that extender

(a) has, in the rehydrated state,
(i) a total protein content of not less than 16 per cent; and
5-8-82 (ii) a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;
(b) has, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to Division 14 in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively, and
28-1-75 (c) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

Extended Poultry Products

B.22.028. No person shall sell a food that consists of a mixture of poultry product and poultry product extender, unless that food

(a) has a total protein content of not less than 16 per cent, and

(b) has a fat content of not more than 15 per cent, and

the poultry product extender, meets the requirements of paragraphs B.22.027 (a) to (c).

Simulated Poultry Products

B.22.029. No person shall sell a simulated poultry product unless that product

(a) has a total protein content of not less than 16 per cent,

5-8-82 (b) has a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981,

(c) has a fat content of not more than 15 per cent,

28-1-75 (d) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to Division 14 in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively, and

(e) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

28-4-77 **Egg Products**

B.22.032. No person shall sell any product simulating whole egg unless that product

(a) is made from liquid, dried or frozen egg albumen or mixtures thereof;

5-8-82 (b) has a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(c) notwithstanding sections D.01.009 and D.02.009, contains, per 100 grams on a ready-to-use basis,

(i) not less than

(A) 50 milligrams calcium,

(B) 2.3 milligrams iron,

(C) 1.5 milligrams zinc,

(D) 130 milligrams potassium,

(E) 1000 International Units Vitamin A,

(F) 0.10 milligram thiamine,

22-7-75 (G) 0.30 milligram riboflavin,

(H) 3.60 milligrams niacin,

(I) 1.60 milligrams pantothenic acid,

(J) 0.20 milligram Vitamin B_6,

(K) 0.50 microgram Vitamin B_{12},

(L) 0.02 milligram folic acid, and

(M) 2.0 International Units alpha tocopherol, and

(ii) not more than 3 milligrams cholesterol;

(d) has a calcium to phosphorous ratio of not less than one part calcium to four parts phosphorous; and

(e) contains in the total fat of any fat or oil used not less than 40 per cent cis-cis methylene interrupted polyunsaturated fatty acids and not more than 20 per cent saturated fatty acids.

5-8-82 **B.22.033.** No person shall sell any egg product referred to in sections B.22.032, B.22.034, B.22.035, B.22.036 and B.22.037 for use as food unless it is free from bacteria of the genus *Salmonella*, as determined by official method MFO-6, Microbiological Examination of Egg Products and Liquid Eggs, November 30, 1981.

B.22.034. [S]. Liquid Whole Egg, Dried Whole Egg or **Frozen Whole Egg**

28-4-77 (a) shall be the product obtained by removing the shell from wholesome fresh eggs or wholesome stored eggs, and

(i) in the case of dried whole egg, drying the product, or

(ii) in the case of frozen whole egg, freezing the product; and

(b) may

(i) contain aluminum sulphate, pH adjusting agents and the colour beta carotene,

(ii) in the case of liquid whole egg destined for drying, contain yeast autolysate and may be treated with hydrogen peroxide and catalase, glucose oxidase and catalase or yeast and suitable glucose fermenting bacterial culture, or

(iii) in the case of dried whole egg, contain anti-caking agents.

B.22.035. [S]. Liquid Yolk, Dried Yolk or **Frozen Yolk**

(a) shall be the product obtained by removing the shell and egg-white from wholesome fresh eggs or wholesome stored eggs, and
  (i) in the case of dried yolk, drying the product, or
  (ii) in the case of frozen yolk, freezing the product, and

(b) may
  (i) contain aluminum sulphate, pH adjusting agents and the colour beta carotene,
  (ii) in the case of liquid yolk destined for drying, contain yeast autolysate and may be treated with hydrogen peroxide and catalase, glucose oxidase and catalase or yeast and suitable glucose fermenting bacterial culture, or
  (iii) in the case of dried yolk, contain anti-caking agents.

B.22.036. [S]. Liquid Egg-White, (Liquid Albumen), Dried Egg-White, (Dried Albumen) or **Frozen Egg-White (Frozen Albumen)**

(a) shall be the product obtained by removing the shell and yolk from wholesome fresh eggs or wholesome stored eggs, and
  (i) in the case of dried egg-white, drying the product, or
  (ii) in the case of frozen egg-white, freezing the product; and

28-4-77

(b) may
  (i) contain whipping agents, aluminum sulphate and pH adjusting agents,
  (ii) in the case of liquid egg-white destined for drying, contain yeast autolysate and may be treated with hydrogen peroxide and catalase, glucose oxidase and catalase or yeast and suitable glucose fermenting bacterial culture,
  (iii) in the case of liquid egg-white and dried egg-white, contain lipase or pancreatin, or
  (iv) in the case of dried egg-white, contain anti-caking agents.

B.22.037. [S]. Liquid Whole Egg Mix, Dried Whole Egg Mix, Frozen Whole Egg Mix, Liquid Yolk Mix, Dried Yolk Mix or **Frozen Yolk Mix**

(a) shall be the product obtained by adding salt, sweetening agent or both to Liquid Whole Egg, Dried Whole Egg, Frozen Whole Egg, Liquid Yolk, Dried Yolk or Frozen Yolk; and
(b) may, in the case of dried whole egg mix or dried yolk mix, contain anti-caking agents.

B.22.038. (1) No person shall use a common name referred to in sections B.22.034 to B.22.037 for an egg product that has been subjected to a process, other than a process referred to in those sections, if that process results in a decrease in the amount of a vitamin or mineral nutrient that before processing was present in 100 g of the egg product in an amount equal to at least 10 per cent of the weighted recommended nutrient intake, unless the amount of the vitamin or mineral nutrient is restored to the amount that was present before processing.

14-5-96

(2) Notwithstanding sections D.01.009, D.01.011 and D.02.009, a person may add any vitamin or mineral nutrient referred to in column II of item 27 of the table to section D.03.002 to any egg product referred to in sections B.22.034 to B.22.037 to restore the vitamin or mineral nutrient to the amount that was present in the egg product before processing.

(3) In this section, "weighted recommended nutrient intake" has the same meaning as in subsection D.01.001(1).

*(R) Minor correction

Food Packaging Materials

B.23.001. No person shall sell any food in a package that may yield to its contents any substance that may be injurious to the health of a consumer of the food.

B.23.002. Subject to section B.23.003 no person shall sell any food in a package that has been manufactured from a polyvinyl chloride formulation containing an octyltin chemical.

4-12-86 **B.23.003.** A person may sell food, other than milk, skim milk, partly skimmed milk, sterilized milk, malt beverages and carbonated non-alcoholic beverage products, in a package that has been manufactured from a polyvinyl chloride formulation containing any or all of the octyltin chemicals, namely, di (**n**-octyl)tin S,S'-bis(isooctylmercaptoacetate), di (**n**-octyl)tin maleate polymer and (**n**-octyl)tin S,S',S"-tris (isooctylmercaptoacetate) if the proportion of such chemicals, either singly or in combination, does not exceed a total of 3 per cent of the resin, and the food in contact with the package contains not more than 1 part per million total octyltin.

B.23.004. (1) Di (**n**-octyl)tin S,S'-bis (isooctylmercaptoacetate) shall be the octyltin chemical made from di (**n**-octyl)tin dichloride and shall contain 15.1 to 16.4 per cent of tin and 8.1 to 8.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, di (**n**-octyl)tin dichloride shall be the chemical having an organotin composition of not less than 95 per cent di (**n**-octyl)tin dichloride and shall contain not more than 4-12-86

(a) 5 per cent total of **n**-octyltin trichloride or tri (**n**-octyl)tin chloride or both;
(b) 0.2 per cent total of other eight (8) carbon isomeric alkyltin derivatives; and
(c) 0.1 per cent total of the higher and lower homologous alkyltin derivatives.

B.23.005. Di (**n**-octyl)tin maleate polymer shall be the octyltin chemical made from di (**n**-octyl)tin dichloride and shall have the formula ((C8H17)2SnC4H2O4)n (where **n** is between 2 and 4 inclusive), and a saponification number of 225 and 255, and shall contain 25.2 to 26.6 per cent of tin.

B.23.006. (1) (**n**-octyl)tin S,S',S"-tris (isooctylmercaptoacetate), being an octyltin chemical having the formula n-C8H17Sn(SCH2CO2C8H17)3, shall be made from (**n**-octyl)tin trichloride and shall contain 13.4 to 14.8 per cent of tin and 10.9 to 11.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, (**n**-octyl)tin trichloride shall be the chemical having an organotin composition of not less than 95 per cent (**n**-octyl)tin trichloride and shall contain not more than 4-12-86

(a) 5 per cent total of di (**n**-octyl)tin dichloride, tri (**n**-octyl)tin chloride or the higher (more than eight (8) carbons) alkyltin chlorides or any combination of the foregoing.
(b) 0.2 per cent total of alkyl tin derivatives; and
(c) 0.1 per cent of the lower (less than eight carbons) homologous alkyltin derivatives.

5-8-82 **B.23.007.** No person shall sell a food in a package that may yield to its contents any amount of vinyl chloride, as determined by official method FO-40, Determination of Vinyl Chloride in Food, October 15, 1981, in respect of that food.

27-5-82 **B.23.008.** No person shall sell a food in a package that may yield to its contents any amount of acrylonitrile as determined by official method, FO-41, Determination of Acrylonitrile in Food, February 16, 1982, in respect of that food.

30-8-78 **Foods for Special Dietary Use**

B.24.001. In this Division,

"**expiration date**" means, in respect of a formulated liquid diet, a food represented for use in a very low-energy diet, a meal replacement or a nutritional supplement, the date

3-10-95 (a) after which the manufacturer does not recommend that it be consumed, and

(b) up to which it maintains its microbiological and physical stability and the nutrient content declared on the label; (*date limite d'utilisation*)

"**food for special dietary use**" means food that has been specially processed or formulated to meet the particular requirements of a person

(a) in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or

30-8-78 (b) for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods; (*aliment à usage diététique spécial*)

"**formulated liquid diet**" means a food that

(a) is sold for consumption in liquid form, and

(b) is sold or represented as a nutritionally complete diet for oral or tube feeding of a person described in paragraph (a) of the definition "food for special dietary use"; (*préparation pour régime liquide*)

"**hospital**" means a facility

(a) that is licensed, approved or designated as a hospital by a province, in accordance with the laws of the province, to provide care or treatment to persons suffering from any form of disease or illness, or

(b) that is owned or operated by the government of Canada or of a province and that provides health services;

13-1-94 (*hôpital*)

"**major change**" means, in respect of a food that is represented for use in a very low energy diet, any change in any of the following, where the manufacturer's experience or generally accepted theory would predict an adverse effect on the levels or availability of nutrients in, the microbiological or chemical safety of or the safe use of the food:

(a) an ingredient or the amount of an ingredient in the food,

(b) the manufacturing process or the packaging of the food, or

(c) the directions for the preparation and use of the food;

(*changement majeur*)

3-10-95 "**meal replacement**" - Revoked by P.C. 1995-1676 of October 3, 1995.

"**pharmacist**" means a person who is registered and entitled under the laws of a province to practise pharmacy and who is practising pharmacy under those laws in that province; (*pharmacien*)

13-1-94 "**physician**" means a person who is registered and entitled under the laws of a province to practise medicine and who is practicing medicine under those laws in that province; (*médecin*)

3-10-95 "**prepackaged meal**" - Revoked by P.C. 1995-1676 of October 3, 1995.

"**target body weight**" means the anticipated body weight at the end of the weight reduction diet, as determined by the physician before the weight reduction diet begins; (*poids corporel cible*)

13-1-94 "**very low energy diet**" means a diet for weight reduction that provides less than 900 kilocalories per day when followed as directed. (*régime à très faible teneur en énergie*)

15-9-77 **B.24.002.** Revoked by P.C. 1977-2550 of September 15, 1977.

30-1-86 **B.24.003.** (1) No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is a food for special dietary use unless the food is

(a) a carbohydrate-reduced food that meets the requirements contained in section B.24.004;
(b) a sugar-free food that meets the requirements contained in section B.24.005;
18-4-84 (c) a calorie-reduced food that meets the requirements contained in section B.24.006;
(d) a low calorie food that meets the requirements contained in section B.24.007;
(e) a low sodium food that meets the requirements contained in section B.24.008;

12-12-02 * Paragraphs B.24.003 (1) (a) to (e) are repealed by P.C. 2002-2200 of December 12, 2002.

(f) a formulated liquid diet that meets the requirements contained in sections B.24.101 and B.24.102;
3-10-95 (f.1) a meal replacement for special dietary use that meets the requirements contained in section B.24.200;
(f.2) a nutritional supplement that meets the requirements contained in section B.24.201;
1-5-96 (g) a gluten-free food that meets the requirements contained in section B.24.018;
(h) represented for protein-restricted diets;
(i) represented for low (naming the amino acid) diets; or
13-1-94 (j) a food represented for use in a very low energy diet, where the food meets the requirements contained in section B.24.303.

* (1.1) Despite subsection (1), a person may label, package, sell or advertise a food in a manner likely to create an impression that it is a food for special dietary use if its label carries a statement or claim set out in column 4 of the table following section B.01.513, in accordance with section B.01.503, in respect of any of the following subjects set out in column 1:
12-12-02

(a) "free of energy", set out in item 1;
(b) "low in energy", set out in item 2;
(c) "free of sodium or salt", set out in item 31;
(d) "low in sodium or salt", set out in item 32; or
(e) "free of sugars", set out in item 37.

30-8-78 (2) Subsection (1) does not apply to infant formulas.

18-4-84 (3) No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is for use in a weight reduction diet unless that food is

(a) a meal replacement that meets the compositional requirements contained in section B.24.200;
(b) a prepackaged meal;
3-10-95 (c) a food sold by a weight reduction clinic to clients of the clinic for use in a weight reduction program supervised by the staff of the clinic; or
(d) a food represented for use in a very low-energy diet that meets the compositional requirements contained in section B.24.303.

* (4) Except as otherwise permitted by these Regulations, no person shall label, package, sell or advertise a food as "dietetic" or "diet", or use those words as part of the brand name of the food, unless its label carries a statement or claim set out in column 4 of the table following section B.01.513, in accordance with section B.01.503, in respect of any of the following subjects set out in column 1:
12-12-02

(a) "free of energy", set out in item 1;
(b) "low in energy", set out in item 2;
(c) "reduced in energy", set out in item 3;
(d) "lower in energy", set out in item 4; or
(e) "free of sugars", set out in item 37.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

13-6-74

B.24.004. A carbohydrate-reduced food is a food

(a) that would, if it were not carbohydrate-reduced, derive at least 25 per cent of the calories contained in that food from its carbohydrate content; and
(b) that, when ready to serve,
  (i) contains not more than 50 per cent of available carbohydrate normally found in that food when it is not carbohydrate-reduced as determined by an acceptable method, and
  (ii) provides no more calories than would be provided if it were not carbohydrate-reduced.

12-1-78

B.24.005. A sugar-free food is a carbohydrate-reduced food that, when ready to serve,

(a) contains not more than 0.25 per cent available carbohydrate as determined by an acceptable method; and
(b) provides, except in the case of chewing gum, not more than one calorie per 100 grams, or per 100 millilitres of that food.

B.24.006. A calorie-reduced food is a food that, when ready to serve, provides not more than 50 per cent of the calories that would be normally provided in that food if it were not calorie-reduced.

B.24.007. A low calorie food is a food that

(a) is a calorie-reduced food; and
12-1-78 (b) when ready to serve, provides not more than 15 calories per average serving and not more than 30 calories in a reasonable daily intake of that food as set out in Schedule K.

B.24.008. A low sodium food is a food that, when ready to serve, contains

(a) not more than 50 per cent of the sodium that would normally be present in that food if it were not sodium reduced;
(b) not more than 40 milligrams of sodium per 100 grams of food, in the case of foods other than those described in paragraphs (c) and (d);
(c) not more than 80 milligrams of sodium per 100 grams of food, in the case of meat, fish and poultry products;
(d) not more than 50 milligrams of sodium per 100 grams of food, in the case of cheddar cheese, and
14-4-83 (e) except in the case of salt substitutes, no added salts of sodium.

B.24.009. (1) The label and advertisement of a carbohydrate-reduced food shall carry the statement that the food is recommended for "carbohydrate-reduced diets" (*régimes à teneur réduite en glucides*).

12-1-78 (2) The label of a carbohydrate-reduced food shall carry

(a) the expression "carbohydrate-reduced" (*réduite en glucides*) on the principal display panel in close proximity to, and in the same size type as, the common name; and
(b) the following information, shown grouped together and given equal prominence on the label, per serving of stated size, namely,
25-5-93 (i) its energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ), and
  (ii) its protein, fat and carbohydrate content, expressed in grams.

B.24.010. (1) The label and advertisement of a sugar-free food shall carry the statement that the food is recommended for "carbohydrate-reduced diets" (*régimes à teneur réduite en glucides*).

12-1-78 (2) The label of a sugar-free food shall carry

(a) the expression "sugar-free" or "sugarless" (*sans sucre*) on the principal display panel in close proximity to, and in the same size type as, the common name; and
(b) the following information, shown grouped together and given equal prominence on the label, per serving of stated size, namely,
25-5-93 (i) its energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ), and
  (ii) its protein, fat and carbohydrate content, expressed in grams.

B.24.011. (1) The label and advertisement of a calorie-reduced food shall carry the statement that the food is recommended for "calorie-reduced diets" (*régimes à teneur réduite en calories*).

(2) The label of a calorie-reduced food shall carry

12-1-78 (a) the expression "calorie-reduced" (*réduit en calories*) on the principal display panel in close proximity to, and in the same size type as, the common name; and

(b) the following information, shown grouped together and given equal prominence on the label, per serving of stated size, namely,

25-5-93 (i) its energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ), and

(ii) its protein, fat and carbohydrate content, expressed in grams.

B.24.012. (1) The label and advertisement of a low calorie food shall carry the statement that the food is recommended for "calorie-reduced diets" (*régimes à teneur réduite en calories*).

12-1-78 (2) The label of a low calorie food shall carry

(a) the expression "low calorie" (hypocalorique) on the principal display panel in close proximity to, and in the same size type as, the common name; and

(b) the following information, shown grouped together and given equal prominence on the label, per serving of stated size, namely,

25-5-93 (i) its energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ), and

(ii) its protein, fat and carbohydrate content, expressed in grams.

B.24.013. (1) The label and advertisement of a low sodium food shall carry the statement that the food is recommended for "sodium-restricted diets" (*régimes à teneur réduite en sodium*).

(2) The label of a low sodium food shall carry

(a) the expression "low sodium" (hyposodique) on the principal display panel in close proximity to, and in the same size type as, the common name; and

(b) the following information, shown grouped together and given equal prominence on the label, per serving of stated size, namely,

4-4-95 (i) its energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) its protein, fat and carbohydrate content, expressed in grams, and

(iii) its sodium and potassium content, expressed in milligrams.

12-1-78 **B.24.014.** For the purposes of this Division, where a common name is used in respect of a food other than the brand or trade name by which it is generally known, the common name shall be shown in close proximity to the brand or trade name in at least one-half the size of the type used for the brand or trade name.

12-12-02 * **B.24.004.** to **B.24.014** of the Regulations are repealed by P.C. 2002-2200 of December 12, 2002.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

31-10-88 **B.24.015.** Revoked by P.C. 1988-2457 of October 31, 1988

31-10-88 **B.24.016.** Revoked by P.C. 1988-2457 of October 31, 1988

13-1-94 **B.24.017.** (1) Where the manufacturer of a formulated liquid diet, a meal replacement or a food represented for use in a very low energy diet is requested in writing by the Director to submit, on or before a specified day, evidence with respect to that product, the manufacturer shall make no further sales of that product after that day unless the manufacturer has submitted the evidence requested.

30-8-78 (2) Where the Director is of the opinion that the evidence submitted by a manufacturer pursuant to subsection (1) is not sufficient, he shall so notify the manufacturer in writing.

13-1-94 (3) Where, pursuant to subsection (2), a manufacturer is notified that the evidence with respect to a formulated liquid diet, a meal replacement or a food represented for use in a very low energy diet is not sufficient, the manufacturer shall make no further sales of that product unless the manufacturer submits further evidence and is notified in writing by the Director that the further evidence is sufficient.

(4) A reference in this section to evidence with respect to a formulated liquid diet, a meal replacement or a food represented for use in a very low energy diet means evidence to establish that the food is nutritionally adequate to be used as the sole source of nutrition in meeting the nutritional needs of a person for whom it is intended, when the food is consumed in accordance with the directions for use.

13-9-95 **B.24.018.** No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food unless the food does not contain wheat, including spelt and kamut, or oats, barley, rye or triticale or any part thereof.

B.24.019. The label of a food that is labelled, packaged, sold or advertised as "gluten-free" shall carry the following information, per serving of stated size of the food:

(a) the energy value of the food, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ); and
(b) the protein, fat and carbohydrate content of the food, expressed in grams.

12-12-02 ***B.24.019.** is repealed by P.C. 2002-2200 of December 12, 2002.

* COMING INTO FORCE: *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

Formulated Liquid Diets

30-8-78 **B.24.100.** No person shall advertise a formulated liquid diet to the general public.

B.24.101. No person shall sell a formulated liquid diet unless the food

(a) if sold ready to serve, or
(b) if not sold ready to serve, when diluted with water, milk, or water and milk,

is a complete substitute for the total diet in meeting the nutritional requirements of a person.

30-8-78 **B.24.102.** (1) Subject to subsection (4), a formulated liquid diet shall contain, when ready to serve,

(a) either
5-8-82 (i) not less than 20 grams of protein of nutritional quality equivalent to casein, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981, or
(ii) such an amount and quality of protein, including those proteins to which amino acids are added, that, when the quality of the protein is expressed as a fraction of the quality of casein,
(A) the fraction will not be less than 85/100, and
(B) the result obtained by multiplying the fraction by the gram weight of the protein will not be less than 20; and
(b) not less than 1 gram linoleic acid in the form of a glyceride.

30-8-78 (2) Notwithstanding sections D.01.009, D.01.011 and D.02.009, a formulated liquid diet shall contain, when ready to serve, the vitamins and minerals named in column I of the table to this section in amounts,

(a) where the recommended intake of the food is 2,500 kilocalories per day or less, not less than the amounts set out in column II and not more than the amounts, if any, set out in column III of that table opposite those vitamins and minerals; and
(b) where the recommended intake of the food is greater than 2,500 kilocalories per day, not less than the amounts set out in column IV and not more than the amounts, if any, set out in column V of that table opposite those vitamins and minerals.

(3) The amounts of the nutrients specified in paragraphs (1)(a) and (b) and subsection (2) shall be calculated

(a) per 1,000 available kilocalories, where the recommended intake of the food is 2,500 kilocalories per day or less; and
(b) per 1,500 available kilocalories, where the recommended intake of the food is greater than 2,500 kilocalories per day.

(4) Paragraph (1)(a) does not apply to a formulated liquid diet represented as being for a protein restricted diet or a low (named amino acid) diet.

TABLE

Column I *Vitamins*	*Per 1,000 available kilocalories* *Column II* *Minimum*	*Column III* *Maximum*	*Per 1,500 available kilocalories* *Column IV* *Minimum*	*Column V* *Maximum*
Vitamin A	2,000 International Units	5,000 International Units	2,000 International Units	3,000 International Units
Vitamin D	100 International Units	400 International Units	100 International Units	200 International Units
Vitamin E (α-tocopherol)	5.0 International Units		5.0 International Units	
Ascorbic Acid	20 milligrams		20 milligrams	
Thiamine	0.5 milligram		0.6 milligram	
Riboflavin	0.7 milligram		0.84 milligram	
Niacin	6.6 milligrams		7.9 milligrams	
Vitamin B_6	0.9 milligram		0.9 milligram	
Vitamin B_{12}	1.5 micrograms		1.5 micrograms	
Folic Acid	100 micrograms		100 micrograms	
12-1-78 *d*-pantothenic Acid	2.5 milligrams		2.5 milligrams	
Calcium	400 milligrams		400 milligrams	
Phosphorus	400 milligrams		400 milligrams	
Iron	8 milligrams		8 milligrams	
Iodine	50 micrograms		50 micrograms	
Magnesium	150 milligrams		150 milligrams	
Copper	1 milligram		1 milligram	
Zinc	7 milligrams		7 milligrams	

B.24.103. The label of a formulated liquid diet shall carry the following information:

(a) a statement that the food is intended to be consumed orally or by tube feeding;

(b) a statement of the energy value of the food, expressed in Calories

(i) per 100 grams or per 100 millilitres of the food as offered for sale, and

(ii) per unit of ready-to-serve food;

(c) a statement of the content in the food of protein or protein equivalent, fat, linoleic acid, available carbohydrate and, where present, crude fibre, expressed in grams

(i) per 100 grams or per 100 millilitres of the food as offered for sale, and

(ii) per unit of ready-to-serve food;

31-10-88 (d) a statement of the content of vitamins and mineral nutrients that are listed in the table to section B.24.102, expressed in International Units or milligrams

(i) per 100 grams or per 100 millilitres of the food as offered for sale, and

(ii) per unit of ready-to-serve food;

(e) a statement of the content of any vitamin or mineral nutrient that is not listed in the table to section B.24.102, expressed in milligrams

(i) per 100 grams or per 100 millilitres of the food as offered for sale, and

(ii) per unit of ready-to-serve food;

(f) complete directions for the preparation and use of the food and for its storage after the container has been opened; and

(g) the expiration date of the formulated liquid diet.

*(R) Minor correction

Meal Replacements, Nutritional Supplements, Prepackaged Meals and Foods Sold by Weight Reduction Clinics

B.24.200. (1) No person shall sell or advertise a meal replacement unless, when in a ready-to-serve form or when prepared according to directions for use, with water, milk, partially skim milk or skim milk, or a combination thereof, it meets the following requirements:

(a) the meal replacement provides a minimum of 225 kcal or 945 kJ per serving;
(b) not less than 15 per cent and not more than 40 per cent of the energy available from the meal replacement is derived from its protein content, except that a meal replacement for use in a weight reduction diet shall derive not less than 20 per cent of its available energy from its protein content;
(c) subject to subsection (2), not more than 35 per cent of the energy available from the meal replacement is derived from its fat content;
(d) not less than 3.0 per cent of the energy available from the meal replacement is derived from linoleic acid in the form of a glyceride and not less than 0.5 per cent of the energy available from the meal replacement is derived from n-3 linolenic acid in the form of a glyceride, and the ratio of linoleic acid to n-3 linolenic acid is not less than 4 to 1 and not more than 10 to 1;
(e) the proteins present in the meal replacement are
    (i) of a nutritional quality equivalent to that of casein, or
    (ii) of a nutritional quality and in an amount sufficient to yield a result of not less than 15 per cent, or not less than 20 per cent in the case of a meal replacement for use in a weight reduction diet, when the nutritional quality of those proteins is divided by the nutritional quality of casein and multiplied by the percentage of energy available from the proteins present in the meal replacement; and
(f) each serving of the meal replacement contains each vitamin and mineral nutrient listed in column I of the table to this section
    (i) subject to subsection (3), in an amount not less than the minimum amount shown for that vitamin or mineral nutrient in column II of the table, and
    (ii) subject to subsections (4) and (5), in an amount that, including overage, is not more than the maximum amount shown for that vitamin or mineral nutrient in column III of the table.

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(2) No person shall sell or advertise a meal replacement that is represented as a replacement for all daily meals unless, when in a ready-to-serve form or when prepared according to directions for use, with water, milk, partially skim milk or skim milk, or a combination thereof, it meets the following requirements:

(a) not more than 30 per cent of the energy available from the meal replacement is derived from its fat content; and
(b) not more than 10 per cent of the energy available from the meal replacement is derived from its saturated fatty acid content.

(3) The minimum amount required under subparagraph (1)(f)(i) for selenium, chromium or molybdenum does not apply in respect of a meal replacement that is not represented as a replacement for all daily meals and that does not contain added selenium, chromium or molybdenum, as the case may be.

(4) A vitamin or mineral nutrient that is not an added ingredient in the meal replacement shall not be taken into account for the purposes of subparagraph (1)(f)(ii).

(5) The maximum amount shown for vitamin C in column III of the table to this section does not include overage.

*(R) Minor correction

TABLE

COLUMN I	*COLUMN II*		*COLUMN III*	
Nutrients	*Minimum Amount per Serving*		*Maximum Amount per Serving*	
VITAMINS				
Vitamin A	250	RE	630	RE
Vitamin D	1.25	µg	2.50	µg
Vitamin E	2.5	mg	5.0	mg
Vitamin C	10	mg	20	mg
Thiamine	300	µg	750	µg
Riboflavin	400	µg	800	µg
Niacin	6	NE	12	NE
Vitamin B_6	400	µg	750	µg
Vitamin B_{12}	0.25	µg	0.75	µg
Folacin	60	µg	120	µg
Pantothenic acid	1.25	mg	2.50	mg
Biotin	25	µg	75	µg
MINERAL NUTRIENTS				
Calcium	200	mg	400	mg
Phosphorus	250	mg	500	mg
Iron	2.5	mg	5.0	mg
Iodide	40	µg	120	µg
Magnesium	60	mg	120	mg
Copper	0.5	mg	1.0	mg
Zinc	3	mg	6	mg
Potassium	375	mg		
Sodium	250	mg		
Manganese	1	mg	2	mg
Selenium	10	µg	20	µg
Chromium	10	µg	20	µg
Molybdenum	20	µg	40	µg

3-10-95

B.24.201. (1) No person shall sell or advertise a nutritional supplement that contains less than 225 kcal or 945 kJ per serving, unless it meets the following requirements:

(a) the nutritional supplement contains at least 150 kcal or 630 kJ per serving;
(b) not less than 15 per cent and no more than 40 per cent of the energy available from the nutritional supplement is derived from its protein content;
(c) the proteins present in the nutritional supplement are
  (i) of a nutritional quality equivalent to that of casein, or
  (ii) of a nutritional quality and in an amount sufficient to yield a result of not less than 15 per cent when the nutritional quality of those proteins is divided by the nutritional quality of casein and multiplied by the percentage of energy available from the proteins present in the nutritional supplement; and
(d) the nutritional supplement contains, per 100 kcal or 420 kJ, each vitamin and mineral nutrient listed in column I of the table to this section
  (i) subject to subsection (3), in an amount not less than the minimum amount shown for that vitamin or mineral nutrient in column II of the table, and
  (ii) subject to subsections (4) and (5), in an amount that, including overage, is not more than the maximum amount shown for that vitamin or mineral nutrient in column III of the table.

(2) No person shall sell or advertise a nutritional supplement that provides 225 kcal or 945 kJ, or more, per serving unless, when in a ready-to-serve form or when prepared according to directions for use, with water, milk, partially skim milk, skim milk, or a combination thereof, it meets the following requirements:

(a) the nutritional supplement provides at least 225 kcal or 945 kJ per serving;
(b) not more than 35 per cent of the energy available from the nutritional supplement is derived from its fat content;

*(R) Minor correction

(c) not less than 3.0 per cent of the energy available from the nutritional supplement is derived from linoleic acid in the form of a glyceride and not less than 0.5 per cent of the energy available from the nutritional supplement is derived from n-3 linolenic acid in the form of a glyceride, and the ratio of linoleic acid to n-3 linolenic acid is not less than 4 to 1 and not more than 10 to 1;

(d) not less than 15 per cent and not more than 40 per cent of the energy available from the nutritional supplement is derived from its protein content;

(e) the proteins present in the nutritional supplement are

(i) of a nutritional quality equivalent to that of casein, or

(ii) of a nutritional quality and in an amount sufficient to yield a result of not less than 15 per cent when the nutritional quality of those proteins is divided by the nutritional quality of casein and multiplied by the percentage of energy available from the proteins present in the nutritional supplement; and

(f) the nutritional supplement contains, per 100 kcal or 420 kJ, each vitamin and mineral nutrient listed in column I of the table to this section

(i) subject to subsection (3), in an amount not less than the minimum amount shown for that vitamin or mineral nutrient in column II of the table, and

(ii) subject to subsections (4) and (5), in an amount that, including overage, is not more than the maximum amount shown for that vitamin or mineral nutrient in column III of the table.

(3) The minimum amount required under subparagraph (1)(d)(i) or (2)(f)(i) for selenium, chromium or molybdenum does not apply in respect of a nutritional supplement that does not contain added selenium, chromium or molybdenum, as the case may be.

(4) A vitamin or mineral nutrient that is not an added ingredient in the nutritional supplement shall not be taken into account for the purposes of subparagraphs (1)(d)(ii) and (2)(f)(ii).

(5) The maximum amount shown for vitamin C in column III of the table to this section does not include overage.

3-10-95

TABLE

COLUMN I	*COLUMN II*		*COLUMN III*	
Nutrients	*Minimum Amount per Available 100 Kcal or 420 kJ*		*Maximum Amount per Available 100 Kcal or 420 kJ*	
VITAMINS				
Vitamin A	100	RE	250	RE
Vitamin D	0.25	µg	1	µg
Vitamin E	1.0	mg	2.0	mg
Vitamin C	5	mg	10	mg
Thiamine	140	µg	350	µg
Riboflavin	180	µg	360	µg
Niacin	3	NE	6	NE
Vitamin B_6	180	µg	350	µg
Vitamin B_{12}	0.1	µg	0.3	µg
Folacin	30	µg	60	µg
Pantothenic acid	0.6	mg	1.2	mg
Biotin	12	µg	35	µg
MINERAL NUTRIENTS				
Calcium	100	mg	175	mg
Phosphorus	100	mg	175	mg
Iron	1.0	mg	2.0	mg
Iodide	15	µg	45	µg
Magnesium	20	mg	40	mg
Copper	0.15	mg	0.30	mg
Zinc	1.4	mg	2.0	mg
Potassium	175	mg		
Manganese	0.45	mg	0.90	mg
Selenium	4	µg	8	µg
Chromium	4	µg	8	µg
Molybdenum	8	µg	15	µg

*(R) Minor correction

B.24.202. The label of a meal replacement or nutritional supplement shall

(a) show the following information per serving of stated size and per stated quantity of food, when prepared according to the directions for use:
  (i) the energy value of the food, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),
  (ii) the protein, fat, linoleic acid, n-3 linolenic acid, saturated fatty acid and carbohydrate contents of the food, expressed in grams,
  (iii) the vitamin A, vitamin D, vitamin E, vitamin C, thiamin or vitamin B_1, riboflavin or vitamin B_2, niacin, vitamin B_6, vitamin B_{12}, folacin and pantothenic acid or pantothenate contents of the food, expressed, in the case of a meal replacement, as a percentage of the recommended daily intake specified in column II of the table to Division 1 of Part D for that vitamin and, in the case of a nutritional supplement, in retinol equivalents (RE) for vitamin A, in niacin equivalents (NE) for niacin and in milligrams for vitamin D, vitamin E, vitamin C, thiamin or vitamin B_1, riboflavin or vitamin B_2, vitamin B_6, vitamin B_{12}, folacin and pantothenic acid or pantothenate,
  (iv) the calcium, phosphorus, iron, iodide, magnesium and zinc contents of the food, expressed, in the case of a meal replacement, as a percentage of the recommended daily intake specified for that mineral nutrient in column II of the table to Division 2 of Part D and, in the case of a nutritional supplement, expressed in milligrams, and
  (v) the biotin, copper, potassium, sodium, manganese, selenium, chromium and molybdenum contents of the food, expressed in milligrams;

(b) in the case of a meal replacement or a nutritional supplement to which milk, partially skim milk or skim milk is to be added, carry a statement that the nutrient content of the food has been determined taking into consideration the milk, partially skim milk or skim milk that will be added according to the directions for use;

(c) in the case of a meal replacement that is sold or advertised as a replacement for all daily meals in a weight reduction diet, include directions for use that would result in a daily energy intake of at least 900 kcal or 3 780 kJ;

(d) include the expiration date of the meal replacement or nutritional supplement;

(e) in the case of a meal replacement for use in a weight reduction diet, carry the statement "USEFUL IN WEIGHT REDUCTION ONLY AS PART OF AN ENERGY-REDUCED DIET / UTILE POUR PERDRE DU POIDS SEULEMENT DANS LE CADRE D'UN RÉGIME À TENEUR RÉDUITE EN ÉNERGIE" prominently displayed on the principal display panel; and

3-10-95 (f) in the case of a meal replacement for use in a weight reduction diet that is not represented as a replacement for all daily meals in a diet, include the information required under section B.24.204.

B.24.203. The label of a prepackaged meal for use in a weight reduction diet or of a food to be sold in a weight reduction clinic shall

(a) show the following information per serving of stated size and per stated quantity of food, when prepared according to directions for use:
  (i) the energy value of the food, expressed in Calories (Calories or Cal) and kilojoules (kilojoules orkJ), and
  (ii) the protein, fat and carbohydrate contents of the food, expressed in grams;

12-12-02 * (a) Repealed by P.C. 2002-2200 of December 12, 2002

(b) carry the statement "USEFUL IN WEIGHT REDUCTION ONLY AS PART OF AN ENERGY-REDUCED DIET / UTILE POUR PERDRE DU POIDS SEULEMENT DANS LE CADRE D'UN RÉGIME À TENEUR RÉDUITE EN ÉNERGIE" prominently displayed on the principal display panel; and

(c) include the information required under section B.24.204.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

B.24.204. The label of a prepackaged meal, or of a meal replacement other than a meal replacement represented as a replacement for all daily meals in a diet, that is packaged, sold or advertised for use in a weight reduction diet, or of a food to be sold in a weight reduction clinic, shall include, in the directions for use, a sample seven-day menu in which the prepackaged meal, meal replacement or food is used and which meets the following requirements:

(a) each daily meal includes a minimum of one serving, as described in Canada's Food Guide to Healthy Eating, published in 1992 by the Department of Supply and Services by authority of the Minister of National Health and Welfare, of one food from each of the following groups:
  (i) milk, milk products or their alternatives,
3-10-95 (ii) meat and meat alternatives,
  (iii) bread and grain products, and
  (iv) vegetables and fruit;

(b) the daily energy intake provided for is not less than 1 200 kcal or 5 040 kJ;

(c) not more than 30 per cent of the total daily energy intake of the seven-day menu is derived from its fat content and not more than 10 per cent of the total daily energy intake of the menu is derived from its saturated fatty acid content;

(d) the mean daily intake of each nutrient listed in column I of the table to this section is not less than the amount shown in column II, in the case of a menu recommended for men, or in column III, in the case of a menu recommended for women; and

(e) the menu does not include any reference to vitamin or mineral supplements.

TABLE

COLUMN I	*COLUMN II*		*COLUMN III*	
	MEAN DAILY INTAKE			
Nutrients	*Men*		*Women*	
Protein	65	g	55	g
VITAMINS				
Vitamin A	1 000	RE	800	RE
Vitamin D	5	µg	5	µg
Vitamin E	10	mg	7	mg
Vitamin C	40	mg	30	mg
Thiamin	1	mg	1	mg
Riboflavin	1	mg	1	mg
Niacin	14	NE	14	NE
Vitamin B_6	1.5	mg	1.5	mg
Vitamin B_{12}	1	µg	1	µg
Folacin	230	µg	200	µg
Pantothenic Acid	5	mg	5	mg
3-10-95 **MINERAL NUTRIENTS**				
Calcium	800	mg	800	mg
Phosphorus	1 000	mg	850	mg
Iron	9	mg	13	mg
Iodide	160	µg	160	µg
Magnesium	250	mg	210	mg
Copper	2	mg	2	mg
Zinc	12	mg	9	mg

*(R) Minor correction

B.24.205. (1) No person shall label, package, sell or advertise a prepackaged meal or meal replacement for use in a weight reduction diet, or a food to be sold in a weight reduction clinic, in a manner likely to create an impression that consumption of a vitamin or mineral supplement must be part of a weight reduction diet.

(2) No person shall, on a label of or in advertisement for a prepackaged meal or meal replacement for use in a weight reduction diet, or a food to be sold in a weight reduction clinic, make any direct or indirect reference to a vitamin or mineral supplement.

(3) Every person who advertises a prepackaged meal or meal replacement for use in a weight reduction diet, or a food to be sold in a weight reduction clinic, shall include in the advertisement the statement "USEFUL IN WEIGHT REDUCTION ONLY AS PART OF AN ENERGY-REDUCED DIET / UTILE POUR PERDRE DU POIDS SEULEMENT DANS LE CADRE D'UN RÉGIME À TENEUR RÉDUITE EN ÉNERGIE".

Foods Represented for Use in Very Low Energy Diets

B.24.300. No person shall advertise to the general public a food represented for use in a very low energy diet.

13-1-94

B.24.301. (1) No person shall sell, without a written order from a physician, a food represented for use in a very low energy diet.

(2) Notwithstanding subsection (1), a person may sell, without a written order from a physician, a food represented for use in a very low energy diet to

(a) a physician;

13-1-94

(b) a wholesale druggist;
(c) a pharmacist; or
(d) a hospital.

(3) No person other than a pharmacist shall sell to the general public a food represented for use in a very low energy diet.

B.24.302. A pharmacist shall retain the written order of a physician for a food represented for use in a very low energy diet for at least two years after the date on which the order is filled.

B.24.303. (1) A food represented for use in a very low energy diet, whether ready to serve or diluted with water according to the manufacturer's directions, shall provide, per daily allowance recommended by the manufacturer

(a) either
  (i) not less than 60 g of protein of a nutritional quality equivalent to that of casein, or
  (ii) such an amount and quality of protein that, when the quality of the protein is expressed as a fraction of the quality of casein,
    (A) the fraction is not less than 85/100, and
    (B) the product obtained by multiplying the fraction by the gram weight of the protein is not less than 60;
(b) each vitamin or mineral nutrient named in column I of an item of the table to this subsection, in an amount not less than the minimum amount per day set out in column II of that item; and
(c) any nutritive substance added to the food other than those referred to in paragraph (a) or (b), in an amount that is appropriate for the purpose of the substance in the food as determined from clinical trials.

TABLE

Item	Column I Vitamin or Mineral Nutrient	Column II Minimum amount per day
1.	Thiamine	1.3 mg
2.	Riboflavin	1.6 mg
3.	Niacin	23 mg
4.	Folacin	0.22 mg
5.	Biotin	0.15 mg
6.	Pantothenic acid	7.0 mg
7.	Vitamin B_6	1.5 mg
8.	Vitamin B_{12}	0.001 mg
9.	Vitamin A	1000 RE
10.	Vitamin D	0.005 mg
11.	Vitamin E	10 mg
12.	Vitamin C	40 mg
13.	Calcium	800 mg
14.	Phosphorus	1000 mg
15.	Magnesium	250 mg
16.	Iron	13 mg
17.	Iodine	0.16 mg
18.	Zinc	12 mg
19.	Copper	2 mg
20.	Manganese	3.5 mg
21.	Selenium	0.07 mg
22.	Chromium	0.05 mg
23.	Molybdenum	0.1 mg
24.	Sodium	2000 mg
25.	Potassium	3000 mg
26.	Chloride	1500 mg

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(2) Notwithstanding paragraph (1)(a), a food represented for use in a very low energy diet shall be accompanied by directions for use that when followed would result in the daily intake by a person of at least 1.2g of protein per kilogram target body weight.

B.24.304. The label of a food represented for use in a very low energy diet shall carry the following information:

(a) a statement of the energy value of the food, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ) per 100 g or 100 mL of the food as offered for sale and per unit of ready-to-serve food;
(b) a statement of the content in the food of protein, fat, carbohydrate and, where present, fibre expressed in grams per 100 g or 100 mL of the food as offered for sale and per unit of ready-to-serve food;
(c) a statement of the content in the food of all those vitamins and mineral nutrients that are listed in the table to subsection B.24.303(1) expressed in milligrams, in the case of vitamin A expressed in retinol equivalents (RE), per 100 g or 100 mL of the food as offered for sale and per unit of ready-to-serve food;
(d) a statement of the content in the food of any other nutritive substance added to the food in an amount described in paragraph B.24.303(1)(c), expressed in milligrams or in grams per 100 g or 100 mL of the food as offered for sale and per unit of ready-to-serve food;
(e) the statement "**USE ONLY UNDER MEDICAL SUPERVISION**" prominently displayed on the principal display panel;
(f) directions for use of the food, including
  (i) a statement of the rationale for the use of the food,
  (ii) criteria to be used for the selection of the persons to whom the food may be prescribed,
  (iii) instructions for consultation with and evaluation of the patient and patient follow-up, and
  (iv) a statement concerning adequate precautions and contra-indications;
(g) directions for the preparation of the food, and storage instructions for the food before and after the container has been opened; and
(h) the expiration date of the food.

*(R) Minor correction

B.24.305. (1) No person shall sell or advertise for sale a food represented for use in a very low energy diet unless the manufacturer, at least 90 days before the sale or advertisement, notifies the Director in writing of the intention to sell the food or advertise the food for sale.

(2) The notification referred to in subsection (1) shall be signed by the manufacturer and shall include, in respect of the food represented for use in a very low energy diet, the following information:

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(a) the name under which the food is to be sold or advertised for sale;
(b) the name and address of the principal place of business of the manufacturer;
(c) the name and address of each establishment in which the food is manufactured;
(d) a list of the ingredients of the food, stated quantitatively;
(e) the specifications for nutrient, microbiological and physical quality for each ingredient and for the food;
(f) details of quality control procedures respecting the testing of the ingredients and of the food;
(g) details of the manufacturing process and quality control procedures used throughout the process;
(h) the results of tests carried out to determine the expiration date of the food;
(i) the evidence relied on to establish that the food meets the nutritional requirements, other than energy requirements, of a person for whom it is intended, when the food is consumed in accordance with the directions for use;
(j) a description of the type of packaging to be used;
(k) directions for use;
(l) the written text of all labels, including package inserts, to be used in connection with the food; and
(m) the name and title of the person who signed the notification and the date of signature.

(3) Notwithstanding subsection (1), a person may sell or advertise for sale a food represented for use in a very low energy diet, if the Director, after having been notified by the manufacturer pursuant to that subsection, has informed the manufacturer in writing that the notification meets the requirements of subsection (2).

B.24.306. (1) No person shall sell or advertise for sale a food represented for use in a very low energy diet that has undergone a major change, unless the manufacturer, at least 90 days before the sale or advertisement, notifies the Director in writing of the intention to sell or advertise for sale the food that has undergone the major change.

(2) The notification referred to in subsection (1) shall be signed by the manufacturer and shall include, in respect of the food represented for use in a very low energy diet that has undergone a major change, the following information:

(a) the name under which the food is to be sold or advertised for sale;
(b) the name and address of the principal place of business of the manufacturer;
(c) a description of the major change;
(d) the evidence relied on to establish that the food meets the nutritional requirements, other than energy requirements, of a person for whom it is intended, when the food is consumed in accordance with the directions for use;

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(e) the evidence relied on to establish that the major change has no adverse effect on the food or its use;
(f) the written text of all labels, including package inserts, to be used in connection with the food; and
(g) the name and title of the person who signed the notification and the date of signature.

(3) Notwithstanding subsection (1), a person may sell or advertise for sale a food represented for use in a very low energy diet that has undergone a major change, if the Director, after having been notified by the manufacturer pursuant to that subsection, has informed the manufacturer in writing that the notification meets the requirements of subsection (2).

Interpretation

B.25.001. In this Division,

15-3-90

"expiration date" means, in respect of a human milk substitute, the date

(a) after which the manufacturer does not recommend that it be consumed, and
(b) up to which it maintains its microbiological and physical stability and the nutrient content declared on the label; (*date limite d'utilisation*)

"human milk substitute" means any food that is represented

(a) for use as a partial or total replacement for human milk and intended for consumption by infants, or
(b) for use as an ingredient in a food referred to in paragraph (a); (*succédané de lait humain*)

"infant" means a person who is under the age of one year; (*bébé*)

"infant food" means a food that is represented for consumption by infants; (*aliment pour bébés*)

"junior (naming a food)" means the named food where it contains particles of a size to encourage chewing by infants, but may be readily swallowed by infants without chewing; ((*nom d'un aliment) pour enfants en bas âge*)

"major change" means, in respect of a human milk substitute, any change of an ingredient, the amount of an ingredient or the processing or packaging of the human milk substitute where the manufacturer's experience or generally accepted theory would predict an adverse effect on the levels or availability of nutrients in, or the microbiological or chemical safety of, the human milk substitute; (*changement majeur*)

15-3-90

"new human milk substitute" means a human milk substitute that is

(a) manufactured for the first time,
(b) sold in Canada for the first time, or
(c) manufactured by a person who manufactures it for the first time; (*succédané de lait humain nouveau*)

"strained (naming a food)" means the named food where it is of a generally uniform particle size that does not require and does not encourage chewing by infants before being swallowed; (*(nom d'un aliment) en purée ou tamisé*).

Infant Foods

B.25.002. No person shall sell or advertise for sale an infant food that is set out in column I of an item of Table I to this Division and contains more than the amount of sodium set out in column II of that item.

8-12-83

B.25.003. (1) Subject to subsection (2), no person shall sell infant food that contains

(a) strained fruit,
(b) fruit juice,
(c) fruit drink, or
(d) cereal,

if sodium chloride has been added to that food.

(2) Subsection (1) does not apply to strained desserts containing any of the foods mentioned in paragraphs (1)(a) to (d).

Human Milk Substitutes and Foods Containing Human Milk Substitutes

15-3-90

B.25.045. The common name of a human milk substitute or a new human milk substitute shall be "infant formula". (*préparation pour nourrissons*)

*(R) Minor correction

B.25.046. (1) No person shall sell or advertise for sale a new human milk substitute unless the manufacturer, at least 90 days before the sale or advertisement, notifies the Director in writing of the intention to sell or advertise for sale the new human milk substitute.

(2) The notification referred to in subsection (1) shall be signed and shall include, in respect of the new human milk substitute, the following information:

(a) the name under which it will be sold or advertised for sale;
(b) the name and the address of the principal place of business of the manufacturer;
(c) the names and addresses of each establishment in which it is manufactured;
(d) a list of all of its ingredients, stated quantitatively;
(e) the specifications for nutrient, microbiological and physical quality for the ingredients and for the new human milk substitute;
15-3-90 (f) details of quality control procedures respecting the testing of the ingredients and of the new human milk substitute;
(g) details of the manufacturing process and quality control procedures used throughout the process;
(h) the results of tests carried out to determine the expiration date of the new human milk substitute;
(i) the evidence relied on to establish that the new human milk substitute is nutritionally adequate to promote acceptable growth and development in infants when consumed in accordance with the directions for use;
(j) a description of the type of packaging to be used;
(k) directions for use;
(l) the written text of all labels, including package inserts, to be used in connection with the new human milk substitute; and
(m) the name and title of the person who signed the notification and the date of signature.

(3) Notwithstanding subsection (1), a person may sell or advertise for sale a new human milk substitute if the manufacturer has notified the Director pursuant to subsection (1) and is informed in writing by the Director that the notification is satisfactory.

B.25.047. Sections B.25.051 to B.25.058 apply in respect of new human milk substitutes.

12-12-02 ***B.25.047.** Sections B.25.051 to B.25.059 apply in respect of new human milk substitutes.

B.25.048. (1) No person shall sell or advertise for sale a human milk substitute that has undergone a major change unless the manufacturer of the human milk substitute, at least 90 days before the sale or advertisement, notifies the Director in writing of the intention to sell or advertise for sale the human milk substitute.

(2) The notification referred to in subsection (1) shall be signed and shall include, in respect of the human milk substitute, the following information:

15-3-90 (a) the name under which it will be sold or advertised for sale;
(b) the name and the address of the principal place of business of the manufacturer;
(c) a description of the major change;
(d) the evidence relied on to establish that the human milk substitute is nutritionally adequate to promote acceptable growth and development in infants when consumed in accordance with the directions for use;
(e) the evidence relied on to establish that the major change has had no adverse effect on the human milk substitute;
(f) the written text of all labels, including package inserts, to be used in connection with the human milk substitute; and
(g) the name and title of the person who signed the notification and the date of signature.

(3) Notwithstanding subsection (1), a person may sell or advertise for sale a human milk substitute that has undergone a major change if the manufacturer has notified the Director pursuant to subsection (1) and is informed in writing by the Director that the notification is satisfactory.

*** COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

B.25.051. (1) No person shall sell or advertise for sale a human milk substitute unless, when prepared according to directions for use, it complies with the provisions of this Division respecting human milk substitutes.

(2) No person shall sell or advertise for sale a food that is represented as containing a human milk substitute unless the human milk substitute portion of the food complies with the nutritional requirements set out in this Division for human milk substitutes.

B.25.052. (1) No person shall sell or advertise for sale a human milk substitute unless it meets the nutritional requirements of infants with normal or special dietary needs and it is of such a consistency that, when ready-to-serve, it passes freely through a nursing bottle nipple.

(2) No person shall sell or advertise for sale a food that is represented as containing a human milk substitute unless the human milk substitute portion of the food meets the nutritional requirements of infants with normal or special dietary needs.

B.25.053. (1) No person shall sell or advertise for sale a human milk substitute that requires, when prepared according to directions for use, the addition of a nutritive substance, other than water or a source of carbohydrate or both.

(2) No person shall sell or advertise for sale a food represented as containing a human milk substitute that requires, when prepared according to directions for use, the addition of a nutritive substance other than water.

B.25.054. (1) Except as otherwise provided in this Division, no person shall sell or advertise for sale a human milk substitute unless it contains, when prepared according to directions for use,

(a) per 100 available kilocalories
  (i) not less than 3.3 and not more than 6.0 grams of fat,
  (ii) not less than 500 milligrams of linoleic acid in the form of a glyceride,
  (iii) not more than 1 kilocalorie from C22 Monoenoic Fatty Acids,
  (iv) not less than 1.8 and not more than 4.0 grams of protein,
  (v) not less than 1.8 grams of protein of nutritional quality equivalent to casein, or such an amount and quality of protein, including those proteins to which amino acids are added, that, when the quality of the protein is expressed as a fraction of the quality of casein,
    (A) the fraction will not be less than 85/100, and
    (B) the product obtained by multiplying the fraction by the gram weight of the protein will not be less than 1.8,
  (vi) notwithstanding sections D.01.010, D.01.011 and D.02.009, the vitamin and mineral nutrient set out in column I of an item of Table II to this Division in an amount not less than the amount set out in column II of that item and not more than the amount set out in column III of that item, and
  (vii) not less than 12 milligrams of choline; and

8-12-83 (b) a ratio of
  (i) alpha-tocopherol to linoleic acid of not less than 0.6 International Units to one gram,
  (ii) calcium to phosphorus of not less than 1.2 grams to one gram and not more than 2.0 grams to one gram, and
  (iii) vitamin B_6 to protein of not less than 15 micrograms to one gram.

(2) No person shall sell or advertise for sale a food that is represented as containing a human milk substitute unless the human milk substitute portion of the food complies with subsection (1).

B.25.055. (1) Subparagraph B.25.054(1)(a)(i) does not apply to a human milk substitute represented as being for a fat-modified diet.

(2) Subparagraph B.25.054(1)(a)(iv), except that portion thereof that prescribes the maximum amount of protein, and subparagraph B.25.054(1)(a)(v) do not apply to a human milk substitute represented as being for a low (naming the amino acid) diet.

(3) All that portion of subparagraph B.25.054(1)(a)(vi) that prescribes the minimum amounts of vitamin D, calcium and phosphorus and subparagraph B.25.054(1)(b)(ii) do not apply to a human milk substitute represented as being for a low (naming the mineral) diet or a low vitamin D diet or both.

B.25.056. No person shall sell a human milk substitute or a food that is represented as containing a human milk substitute

(a) that contains an added nutritive substance that is
  (i) normally contained in human milk, and
  (ii) not referred to in paragraph B.25.054(1)(a) unless the amount of that substance present per 100 available kilocalories of the human milk substitute or human milk substitute portion of the food, when prepared according to directions for use, is equal to the amount thereof present per 100 available kilocalories of human milk; or

8-12-83 (b) that contains added amino acids unless
(i) the amino acids are required to improve the quality of the protein in the human milk substitute or human milk substitute portion of the food and are present in an amount not exceeding the minimum required for that purpose, or
(ii) the protein content of the human milk substitute or human milk substitute portion of the food is supplied by isolated amino acids or by protein hydrolysate, or both
and only the L forms of the amino acids have been added.

B.25.057. (1) The label of a human milk substitute shall carry the following information:

31-10-88 (a) a statement of the content of protein, fat, available carbohydrate, ash and, where present, crude fibre in the food
(i) in grams per 100 grams or in grams per 100 millilitres of the human milk substitute as offered for sale, and
(ii) in grams in a stated quantity of the human milk substitute when ready-to-serve;
(b) a statement of the energy value expressed in
(i) calories per 100 grams or calories per 100 millilitres of the human milk substitute as offered for sale, and
(ii) calories in a stated quantity of the human milk substitute when ready-to-serve;
(c) a statement of the quantity of all vitamins and mineral nutrients listed in Table II to this Division
(i) in International Units or milligrams per 100 grams or in International Units or milligrams per 100 millilitres of the human milk substitute as offered for sale, and
(ii) in International Units or milligrams in a stated quantity of the human milk substitute when ready-to-serve;
(d) a statement of the quantity of choline and of any added nutritive substance normally contained in human milk and not referred to in paragraph B.25.054(1)(a)
(i) in milligrams or grams per 100 grams, or in milligrams or grams per 100 millilitres, of the human milk substitute as offered for sale, and
(ii) in milligrams or grams in a stated quantity of the human milk substitute when ready-to-serve;
(e) adequate directions for the preparation, use and storage of the human milk substitute after the container has been opened; and
(f) the expiration date of the human milk substitute.

(2) The label of a food that is represented as containing human milk substitute shall carry the following information:

(a) a statement on the principal display panel of the proportion of the human milk substitute contained in the food as offered for sale in close proximity to any claim regarding the presence of the human milk substitute and given equal prominence to such a claim;
8-12-83 (b) the common name of the human milk substitute in the list of ingredients to be followed by a statement of all the components contained in the human milk substitute;
(c) a statement of
31-10-88 (i) the content of protein, fat, available carbohydrate, ash and, where present, crude fibre contained in the human milk substitute portion of the food, expressed in grams per 100 grams or per 100 millilitres of the human milk substitute portion of the food as offered for sale,
(ii) the energy value of the human milk substitute portion of the food expressed in calories per 100 grams or in calories per 100 millilitres of the human milk substitute portion of the food as offered for sale,
(iii) the quantity of all the vitamins and mineral nutrients set out in Table II to this Division that are contained in the human milk substitute portion of the food in International Units or milligrams per 100 grams or in International Units or milligrams per 100 millilitres of the human milk substitute portion of the food as offered for sale, and
(iv) the quantity of choline and of any added nutritive substance normally contained in human milk and not referred to in paragraph B.25.054(1)(a) contained in the human milk substitute portion of the food in milligrams or grams per 100 grams or in milligrams or grams per 100 millilitres of the human milk substitute portion of the food as offered for sale;
(d) a statement of
31-10-88 (i) the content of protein, fat, available carbohydrate, ash and, where present, crude fibre, expressed in grams per 100 grams or per 100 millilitres of the food as offered for sale and in grams per stated quantity of ready-to-serve food,
(ii) the energy value expressed in calories per 100 grams or in calories per 100 millilitres of the food as offered for sale and in grams per a stated quantity of the food when ready-to-serve,
(iii) the quantity of all vitamins and mineral nutrients set out in Table II to this Division in International Units or milligrams per 100 grams or in International Units or milligrams per 100 millilitres of the food as offered for sale and in International Units or milligrams in a stated quantity of the food when ready-to-serve, and
(iv) the quantity of choline and of any added nutritive substance normally contained in human milk and not referred to in paragraph B.25.054(1)(a) in milligrams or grams per 100 grams or in milligrams or grams per 100 millilitres of the food as offered for sale and in milligrams or grams in a stated quantity of the food when ready-to-serve;

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(e) adequate directions for the preparation, use and storage of the food after the container has been opened; and

(f) the expiration date of the food.

B.25.058. Notwithstanding section D.02.005, no person shall make any claim with respect to the iron content of a human milk substitute except as required by paragraph B.25.057(1)(c), unless the human milk substitute contains at least 1 milligram of iron per 100 available kilocalories.

11-8-88

B.25.059. Revoked by P.C. 1988-1609 of August 11, 1988.

***B.25.059.** No person shall, on the label of or in any advertisement for a human milk substitute or a food represented as containing a human milk substitute, make any statement or claim relating to the content in the food of

(a) the percentage of the daily value of

(i) fat,

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(ii) saturated fatty acids and *trans* fatty acids,

(iii) sodium,

(iv) potassium,

(v) carbohydrate,

(vi) fibre, or

(vii) cholesterol; or

(b) the number of Calories from

(i) fat, or

(ii) saturated fatty acids and *trans* fatty acids.

B.25.060. (1) Where the manufacturer of a human milk substitute or of a food that is represented as containing a human milk substitute is requested in writing by the Director to submit on or before a specified day evidence with respect to the human milk substitute, the manufacturer shall make no further sales of that human milk substitute or food that is represented as containing human milk substitute after that day unless he has submitted the evidence requested.

(2) Where the Director is of the opinion that the evidence submitted by a manufacturer pursuant to subsection (1) is not sufficient, he shall notify the manufacturer in writing that the evidence is not sufficient.

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(3) Where, pursuant to subsection (2), a manufacturer is notified that the evidence with respect to the human milk substitute is not sufficient, he shall make no further sales of that human milk substitute or of that food that is represented as containing the human milk substitute unless he submits further evidence and is notified in writing by the Director that the further evidence is sufficient.

(4) In this section "evidence with respect to the human milk substitute" means

15-3-90

(a) evidence that establishes that the human milk substitute is nutritionally adequate to promote acceptable growth and development in infants when consumed in accordance with the directions for use; and

(b) the results of tests carried out to determine the expiration date of the human milk substitute.

B.25.061. (1) Subject to subsection (2), no person shall include on the label of a food any representation respecting the consumption of the food by an infant who is less than 6 months of age.

15-3-90

(2) Subsection (1) does not apply in respect of a human milk substitute or a new human milk substitute.

* **Coming into force:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

B.25.062. (1) Subject to subsection (2), no person shall sell a food that is labelled or advertised for consumption by infants if the food contains a food additive.

8-12-83

(2) Subsection (1) does not apply to

(a) bakery products that are labelled or advertised for consumption by infants;

9-12-97

(b) ascorbic acid used in cereals containing banana and fruit purees that are labelled or advertised for consumption by infants;

(c) soyabean lecithin used in rice cereal labelled or advertised for consumption by infants;

(d) citric acid used in foods that are labelled or advertised for consumption by infants;

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(e) infant formula that contains the food additives set out in Tables IV and X to section B.16.100 for use in infant formula; or

(f) infant formula that contains ingredients manufactured with food additives set out in Table V to section B.16.100.

TABLE I

SODIUM CONTENT IN INFANT FOODS

Column I *Food*	*Column II* *Total Sodium in Grams per 100 Grams of Food*
1. Junior Desserts	0.10
2. Junior Meat, Junior Meat Dinners, Junior Dinners, Junior Breakfasts	0.25
3. Junior Vegetables, Junior Soups	0.20
4. Strained Desserts	0.05
5. Strained Meats, Strained Meat Dinners, Strained Dinners, Strained Breakfasts	0.15
6. Strained Vegetables, Strained Soups	0.10

TABLE II

Item No.	*Column I* *Vitamin or Mineral nutrient*	*Column II* *Minimum amount per 100 available kilocalories*	*Column III* *Maximum amount per 100 available kilocalories*
B.1	Biotin	2 mcg	--
F.1	Folic Acid	4 mcg	--
N.1	Niacin	250 mcg	--
P.1	d-pantothenic acid	300 mcg	--
R.1	Riboflavin	60 mcg	--
T.1	Thiamine	40 mcg	--
T.2	Alpha-tocopherol	0.6 I.U.	--
V.1	Vitamin A	250 I.U.	500 I.U.
V.2	Vitamin B_6	35 mcg	--
V.3	Vitamin B_{12}	0.15 mcg	--
V.4	Vitamin C	8 mg	--
V.5	Vitamin D	40 I.U.	80 I.U.
V.6	Vitamin K_1	8 mcg	--
C.1	Calcium	50 mg	--
C.2	Chloride	55 mg	150 mg
C.3	Copper	60 mcg	--
L.1	Iodine	5 mcg	--
L.2	Iron	0.15 mg	--
M.1	Magnesium	6 mg	--
M.2	Manganese	5 mcg	--
P.2	Phosphorous	25 mg	--
P.3	Potassium	80 mg	200 mg
S.1	Sodium	20 mg	60 mg
Z.1	Zinc	0.5 mg	--

8-12-83

*(R) Minor correction

Food Irradiation

Interpretation

B.26.001. In this Division,

"**ionizing radiation**" means
(a) gamma-radiation from a Cobalt-60 or Cesium-137 source,
(b) X-rays generated from a machine source operated at or below an energy level of 5 MeV, and
(c) electrons generated from a machine source operated at or below an energy level of 10 MeV; (*rayonnement ionisant*)

"**irradiation**" means treatment with ionizing radiation. (*irradiation*)

Application

B.26.002. This Division does not apply to foods exposed to ionizing radiation from a measuring instrument used to determine weight, estimate bulk solids, measure the total solids in liquids or perform other inspection procedures.

General

B.26.003. (1) Subject to subsection (2), no person shall sell a food that has been irradiated.

(2) A food set out in column I of an item of the table to this Division that has been irradiated may be sold if
(a) the food was irradiated from a source set out in column II of that item for the purpose set out in column III of that item; and
(b) the dose of ionizing radiation absorbed by the food is within the permitted absorbed dose set out in column IV of that item.

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Records

B.26.004. (1) A manufacturer who sells a food that has been irradiated shall keep on his premises, for at least two years after the date of the irradiation, a record containing the following information:

(a) the food irradiated and the quantity and lot numbers of the food;
(b) the purpose of the irradiation;
(c) the date of the irradiation;
(d) the dose of ionizing radiation absorbed by the food;
(e) the source of the ionizing radiation; and
(f) a statement indicating whether the food was irradiated prior to the irradiation by the manufacturer and, if so, the information referred to in paragraphs (a) to (e) in respect of that prior irradiation.

(2) Every person who imports a food that is intended for sale in Canada that has been irradiated shall keep on his premises a record of the information referred to in subsection (1) for at least two years after the date of importation.

Changes to the Table

B.26.005. A request that a food be added or a change made to the table to this Division shall be accompanied by a submission to the Director containing the following information:

(a) the purpose and details of the proposed irradiation, including the source of ionizing radiation and the proposed frequency of and minimum and maximum dose of ionizing radiation;
(b) data indicating that the minimum dose of ionizing radiation proposed to be used accomplishes the intended purpose of the irradiation and the maximum dose of ionizing radiation proposed does not exceed the amount required to accomplish the purpose of the irradiation;
(c) information on the nature of the dosimeter used, the frequency of the dosimetry on the food and data pertaining to the dosimetry and phantoms used to assure that the dosimetry readings reflect the dose absorbed by the food during irradiation;
(d) data indicating the effects, if any, on the nutritional quality of the food, raw and ready-to-serve, under the proposed conditions of irradiation and any other processes that are combined with the irradiation;

(e) data establishing that the irradiated food has not been significantly altered in chemical, physical or microbiological characteristics to render the food unfit for human consumption;
(f) where the Director so requests, data establishing that the proposed irradiation is safe under the conditions proposed for the irradiation;
(g) the recommended conditions of storage and shipment of the irradiated food including the time, temperature and packaging and a comparison of the recommended conditions for the same food that has not been irradiated;
(h) details of any other processes to be applied to the food prior to or after the proposed irradiation; and
(i) such other data as the Director may require to establish that consumers and purchasers of the irradiated food will not be deceived or misled as to the character, value, composition, merit or safety of the irradiated food.

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TABLE

Item	*Column I* *Food*	*Column II* *Permitted Sources of Ionizing Radiation*	*Column III* *Purpose of Treatment*	*Column IV* *Permitted Absorbed Dose*
1.	Potatoes (*Solanum tuberosum L.*)	Cobalt-60	To inhibit sprouting during storage	0.15 kGy max.
2.	Onions (*Allium cepa*)	Cobalt-60	To inhibit sprouting during storage	0.15 kGy max.
3.	Wheat, Flour, Whole Wheat Flour (*Triticum sp.*)	Cobalt-60	To control insect infestation in stored food	0.75 kGy max.
4.	Whole or ground spices and dehydrated seasoning preparations	Cobalt-60, Cesium-137, or electrons from machine sources (3 MeV max.)	To reduce microbial load	10.00 kGy max. total overall average dose

Low-Acid Foods Packaged in Hermetically Sealed Containers

B.27.001. In this Division,

"**commercially sterile**" means the condition obtained in a food that has been processed by the application of heat, alone or in combination with other treatments, to render the food free from viable forms of microorganisms, including spores, capable of growing in the food at temperatures at which the food is designed normally to be held during distribution and storage; (*stérilité commerciale*)
"**hermetically sealed container**" means a container designed and intended to be secure against the entry of microorganisms, including spores; (*récipient hermétiquement fermé*)
"**low-acid food**" means a food, other than an alcoholic beverage, where any component of the food has a pH greater than 4.6 and a water activity greater than 0.85; (*aliment peu acide*)
"**refrigeration**" means exposure to a temperature of 4°C or less but does not mean frozen; (*réfrigéré*)
"**shipping container**" means a receptacle, package or wrapper in which containers of food are placed for transportation; (*contenant d'expédition*)
"**water activity**" means the ratio of the water vapour pressure of a food to the vapour pressure of pure water, at the same temperature and pressure. (*activité de l'eau*)

B.27.002. (1) No person shall sell a low-acid food packaged in a hermetically sealed container unless the food is commercially sterile.

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(2) Subsection (1) does not apply in respect of a low-acid food packaged in a hermetically sealed container where

(a) the low-acid food is kept under refrigeration and the statement "Keep Refrigerated" and "Garder au froid" is carried on the principal display panel of the label of its container, as well as on the label of its shipping container; or

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(b) the low-acid food is kept frozen and the statement "Keep Frozen" and "Garder congelé" is carried on the principal display panel of the label of its container, as well as on the label of its shipping container.

(3) Subsection (1) does not apply in respect of tomatoes or tomato products packaged in hermetically sealed containers where the tomatoes or tomato products have a pH of 4.7 or less after heat processing.

B.27.003. No person shall sell a low-acid food packaged in a hermetically sealed container where the container

(a) is swollen;
(b) is not properly sealed; or
(c) has any defect that may adversely affect its hermetic seal.

B.27.004. (1) Where, in the opinion of the Director, the sale of a low-acid food packaged in a hermetically sealed container may contravene section B.27.002 or B.27.003, the Director may, by notice in writing, request that the manufacturer or importer of the food submit, on or before the date specified in the notice, evidence that establishes that the processes used to manufacture, process and package the food rendered and maintained the food commercially sterile.

(2) Where a manufacturer or an importer receives a notice issued pursuant to subsection (1), the manufacturer or importer shall make no further sales of the food on or after the day specified in the notice until he has submitted the evidence requested in that notice.

(3) Where the Director is of the opinion that the evidence submitted by a manufacturer or importer pursuant to subsection (1) is not sufficient, the Director shall notify the manufacturer or importer in writing that the evidence is not sufficient.

(4) Where, pursuant to subsection (3), a manufacturer or importer is notified that the evidence he has submitted is not sufficient, the manufacturer or importer shall make no further sales of the food until he submits further evidence and is notified in writing by the Director that the further evidence is sufficient.

B.27.005. No person shall sell a commercially sterile low-acid food packaged in a hermetically sealed container unless

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(a) the label or container of the food bears a code or lot number that identifies, in a legible and permanent manner,
  (i) the establishment in which the product was rendered commercially sterile, and
  (ii) the day, month and year on which the food was rendered commercially sterile; and

(b) the exact meaning of each item in any code or lot number referred to in paragraph (a) is available to an inspector at the establishment or, where the food is imported, from the importer.

Novel Foods

Interpretation

B.28.001. The definitions in this section apply in this Division.

"**genetically modify**" means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation. (*modifier génétiquement*)
"**major change**" means, in respect of a food, a change in the food that, based on the manufacturer's experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to
(a) the composition, structure or nutritional quality of the food or its generally recognized physiological effects;
(b) the manner in which the food is metabolized in the body; or
(c) the microbiological safety, the chemical safety or the safe use of the food. (*changement majeur*)
"**novel food**" means
(a) a substance, including a microorganism, that does not have a history of safe use as a food;
(b) a food that has been manufactured, prepared, preserved or packaged by a process that
  (i) has not been previously applied to that food, and
  (ii) causes the food to undergo a major change; and
(c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
  (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
  (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
  (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. (*aliment nouveau*)

Pre-market notification

6-10-99

B.28.002. (1) No person shall sell or advertise for sale a novel food unless the manufacturer or importer of the novel food

(a) has notified the Director in writing of their intention to sell or advertise for sale the novel food; and
(b) has received a written notice from the Director under paragraph B.28.003(1)(a) or subsection B.28.003(2).

(2) A notification referred to in paragraph (1)(a) shall be signed by the manufacturer or importer, or a person authorized to sign on behalf of the manufacturer or importer, and shall include the following information:

(a) the common name under which the novel food will be sold;
(b) the name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer;
(c) a description of the novel food, together with
  (i) information respecting its development,
  (ii) details of the method by which it is manufactured, prepared, preserved, packaged and stored,
  (iii) details of the major change, if any,
  (iv) information respecting its intended use and directions for its preparation,
  (v) information respecting its history of use as a food in a country other than Canada, if applicable, and
  (vi) information relied on to establish that the novel food is safe for consumption;
(d) information respecting the estimated levels of consumption by consumers of the novel food;
(e) the text of all labels to be used in connection with the novel food; and
(f) the name and title of the person who signed the notification and the date of signing.

B.28.003. (1) Within 45 days after receiving a notification referred to in paragraph B.28.002(1)(a), the Director shall review the information included in the notification and

(a) if the information establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient; or
(b) if additional information of a scientific nature is necessary in order to assess the safety of the novel food, request in writing that the manufacturer or importer submit that information.

(2) Within 90 days after receiving the additional information requested under paragraph (1)(b) the Director shall assess it and, if it establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient.

General

C.01.001. (1) In this Part

26-9-85 "**acetaminophen product**" has the same meaning as in Division 9; (*produit d'acétaminophène*)

7-11-95 "**adverse drug reaction**" means a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function; (*réaction indésirable à une drogue*)

26-9-85 "**adult standard dosage unit**" has, with reference to a drug, the same meaning as in Division 9; (*dose normale pour adultes*)

"**antibiotic**" means any drug or combination of drugs such as those named in C.01.401 to C.01.592 which is prepared from certain micro-organisms, or which formerly was prepared from micro-organisms but is now made synthetically and which possesses inhibitory action on the growth of other micro-organisms; (*antibiotique*)

"**brand name**" means, with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French,

20-4-93 (a) that is assigned to the drug by its manufacturer,

(b) under which the drug is sold or advertised, and

(c) that is used to distinguish the drug; (*marque nominative*)

7-11-95 "**case report**" means a detailed record of all relevant data associated with the use of a drug in a subject; (*fiche d'observation*)

30-7-87 "**child resistant package**" means a package that meets the requirements of subsection (2); (*emballage protège-enfants*)

29-6-85 "**children's standard dosage unit**" has, with reference to a drug, the same meaning as in Division 9; (*dose normale pour enfants*)

"**common name**" means, with reference to a drug, the name in English or French by which the drug is

20-4-93 (a) commonly known, and

(b) designated in scientific or technical journals, other than the publications referred to in Schedule B to the Act; (*nom usuel*)

"**expiration date**" means the earlier of

19-11-92 (a) the date, expressed at minimum as a year and month, up to and including which a drug maintains its labelled potency, purity and physical characteristics, and

(b) the date, expressed at minimum as a year and month, after which the manufacturer recommends that the drug not be used; (*date limite d'utilisation*)

7-8-96 "**immediate container**" means the receptacle that is in direct contact with a drug; (*récipient immédiat*)

"**internal use**" means ingestion by mouth or application for systemic effect to any part of the body in which the drug comes into contact with mucous membrane; (*usage interne*)

"**official drug**" means any drug

29-12-60 (i) for which a standard is provided in these Regulations, or

(ii) for which no standard is provided in these Regulations but for which a standard is provided in any of the publications mentioned in SCHEDULE B to the Act; (*drogue officielle*)

"**parenteral use**" means administration of a drug means of hypodermic syringe, needle or other instrument through or into the skin or mucous membrane; (*usage parentéral*)

"**per cent**" means per cent by weight unless otherwise stated; (*pour cent*)

25-7-63 "**practitioner**" means a person authorized by the law of a province of Canada to treat patients with any drug listed or described in SCHEDULE F to the Regulations; (*praticien*)

29-12-60 "**prescription**" means an order given by a practitioner directing that a stated amount of any drug or mixture of drugs specified therein be dispensed for the person named in the order; (*ordonnance*)

"**proper name**" means, with reference to a drug, the name in English or French

(i) assigned to the drug in section C.01.002,

(ii) that appears in bold-face type for the drug in these Regulations and, where the drug is dispensed in a form other than that described in this Part the name of the dispensing form,

(iii) specified in the Canadian licence in the case of drugs included in SCHEDULE C or SCHEDULE D to the Act, or

(iv) assigned in any of the publications mentioned in SCHEDULE B to the Act in the case of drugs not included in subparagraphs (i), (ii) or (iii) of this paragraph; (*nom propre*)

26-9-85 "**salicylate product**" has the same meaning as in Division 9; (*produit de salicylate*)

4-12-97 "**serious adverse drug reaction**" means a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death; (*réaction indésirable grave à une drogue*)

7-11-95 "**serious unexpected adverse drug reaction**" means a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug; (*réaction indésirable grave et imprévue à une drogue*)

"**teaspoon**" means, for the purpose of calculation of dosage, a volume of five cubic centimetres. (*cuillerée à thé*)

30-7-87 "**test group**" means a group that meets the requirements of subsection (3). (*groupe d'essai*)

16-8-95 "**withdrawal period**" means the length of time between the last administration of a drug to an animal and the time when tissues or products collected from the treated animal for consumption as food contain a level of residue of the drug that would not likely cause injury to human health. (*délai d'attente*)

(2) A child resistant package is a package that

(a) when tested in accordance with an acceptable method,
- (i) in the case of a test group comprising children, cannot be opened
  - (A) by at least 85 per cent of those children prior to a demonstration to them of the proper means of opening the package, and
  - (B) by at least 80 per cent of those children after the demonstration, and
- (ii) in the case of a test group comprising adults
  - (A) can be opened by at least 90 per cent of those adults, and

30-7-87
  - (B) where the package is designed so that, once opened and reclosed, it continues to meet the requirements of subparagraph (i), can be so reclosed by at least 90 per cent of those adults; or

30-4-96 (b) complies with the requirements of one of the following standards, namely,

1-7-97
- (i) Canadian Standards Association Standard CAN/CSA-Z76.1-M90, entitled *Reclosable Child-Resistant Packages*, published January 1990, as amended from time to time,
- (ii) European Standard EN 28317:1992, entitled *Child-resistant packaging-Requirements and testing procedures for reclosable packages*, as adopted by the European Committee for Standardization on October 30, 1992, recognized by the British Standards Institution, and effective February 15, 1993 and by the Association française de normalisation, and effective December 20, 1992, and which reiterates fully the international standard ISO 8317:1989, as amended from time to time, and
- (iii) *Code of Federal Regulations* (United States), Title 16, Section 1700.15, entitled *Poison prevention packaging standards*, as amended from time to time.

(3) For the purposes of this section, "test group" means

(a) in relation to children, a group of at least 200 children who
- (i) are healthy and have no obvious physical or mental disability,
- (ii) are between 42 and 51 months of age, and
- (iii) represent evenly, within plus or minus 10 per cent, each monthly age between 42 and 51 months calculated to the nearest month; and

30-7-87 (b) in relation to adults, a group of at least 100 adults who
- (i) are healthy and have no obvious physical or mental disability,
- (ii) are between 18 and 45 years of age, and
- (iii) represent evenly, within plus or minus 10 per cent, each yearly age between 18 and 45 years calculated to the nearest year.

30-4-96 (4) For the purpose of this section, an amendment from time to time to a standard referred to in paragraph (2)(b) becomes effective 18 months after the date designated by the competent authority as the effective date for the amendment.

26-8-98 **C.01.001A.** Repealed by P.C. 1998-1461 of August 26, 1998.

C.01.002. The Proper Name of a drug shown opposite an item number in the following Table is the column headed "Chemical Names and Synonyms" shall be the name shown opposite that item number in the column headed "Proper Names":

TABLE

Item No.	Proper Names	Chemical Names and Synonyms
A.1	Acepromazine	2-acetyl-10-(3-dimethylaminopropyl) phenothiazine
A.2	Acetaminophen	**p**-Acetaminophenol, Paracetamol, **p**-Hydroxyacetanilide: N-acetyl-**p**-aminophenol
A.3	Acetanilide: Acetanilid	Acetylaminobenzene: Antifebrin: Phenylacetamide
A.4	Acetylsalicylic acid	Acetylsalicylic acid
A.5	Allopurinol	1-H-Pyrazolo[3,4-**d**]pyrimidin-4-ol: 4-Hydroxypyrazolo(3,4-**d**)pyrimidine
A.6	Amantadine	1-Adamantanamine
A.7	Aminocaproic, acid	6-Aminohexanoic acid
A.8	Aminopterin	N-[4-(2,4-diamino-6-pteridyl methyl) amino-benzoyl]-L-glutamic acid
A.9	Aminopyrine: Amidopyrine	1,5-dimethyl-2-phenyl-4-dimethylamino-3-pyrazolone: Dimethylaminophenazone
A.10	Amitriptyline	3-(3-Dimethylaminopropylidene)-1,2: 4,5-dibenzocycloheptа-1,4-diene
A.11	Azacyclonol	α,α-diphenyl-4-piperidinecarbinol
B.1	Bemegride	3-Ethyl-3-methylglutarimide
B.2	Benactyzine	Dimethylaminoethyl-1,1-diphenylglycolate
B.3	Bendroflumethiazide	3-benzyl-3,4-dihydro-6-(trifluoromethyl)-2H-1,2,4-benzothiadiazine-7-sulfonamide-1,1-dioxide: Bendrofluazide (B.A.N.)
B.4	Betahistine	2-[2-(Methylamino)ethyl] pyridine
B.5	Bethanidine	N-Benzyl-N'N"-dimethylguanidine: 1-Benzyl-2,3-dimethylguanidine
B.6	Bretylium tosylate	N-2-Bromobenzyl-N-ethyl-N,N-dimethyl-ammonium tosylate (Tosylic acid is trivial name for **p**-toluenesulphonic acid)
B.7	Bromisoval	2-monobromoisovalerylurea: Bromisovalum: Bromvalitone
C.1	Calcium Carbimide	Calcium cyanamide
C.2	Captodiamine	4-butylthio-α-phenylbenzyl-2-dimethyl-aminoethylsulfide
C.3	Carisoprodol	N-Isopropyl-2-methyl-2-propyl-1,3-propane-diol dicarbamate
C.4	Carphenazine	1-{10-(3[4-(2-Hydroxyethyl)-1-piperazinyl] propyl)-phenothiazin-2yl}-1-propapone
C.5	Cephaloridine	7-[(2-Thienyl) acetamido]-3-(1-pyridyl-methyl)-3-cephem-4-carboxylic acid betaine
C.6	Chlormezanone	2-(4-chlorophenyl)-3-methyl-4-methathiazanone-1,1-dioxide: Chlormethazone: Chlormethazanone
C.7	Chloromethapyrilene	N,N-dimethyl-N'-(2-pyridly)-N'-(5-chloro-2-thenyl)-ethylenediamine: Chlorothen
C.8	Chlorphentermine	4-Chloro-α,α-dimethylphenethylamine
C.9	Cinchocaine	2-butoxy-N-(2-diethylaminoethyl) cinchoninamide: Dibucaine
C.10	Cinchophen	2-phenylquinoline-4-carboxylic acid: Quinophan
C.11	Clofibrate	Ethyl 2-(**p**-chlorophenoxy)-2-methyl-propionate

391, August 27, 1969
Replaces page 75, February 18, 1969

*(R) Minor correction

TABLE -- Continued

Item No.	Proper Names	Chemical Names and Synonyms
C.12	Clomiphene	1-Chloro-2-[4-(2-diathylaminoethoxy) phenyl]-1,2-diphenylethylene: 2-[**p**-(2-Chloro-1,2-diphenylvinyl)phenoxy] triethylamine
D.1	Desipramine	5-(3-Methylaminopropyl)-10,11-dihydro-5H-dibenz[b,f]azepine
D.2	Diazepam	7-Chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one
D.3	Diethylpropion	1-phenyl-2-diethylaminopropanone-1
D.4	Diphenidol	1,1-Diphenyl-4-piperidinobutan-1-ol
D.5	Disulfiram	Tetraethylthiuram disulphide
E.1	Ectylurea	2-ethyl-*cis*-crotonylurea
E.2	Emylcamate	1-Ethyl-1-methylpropyl carbamate
E.3	Ethacrynic Acid	[2,3-Dichloro-4-(2-methylenebutyryl) phenoxyl] acetic acid: 2,3-Dichloro-4-(2-ethylacryloyl) phenoxyacetic acid
E.4	Ethchlorvynol	3-(2-chlorovinyl)-1-pentyn-3-ol
E.5	Ethinamate	1-ethynylcyclohexyl carbamate
E.6	Ethionamide	2-Ethylisonicotinthioamide
E.7	Ethomoxane	2-**n**-Butylaminomethyl-8-ethoxybenzo-1,4-dioxan
E.8	Ethyl Trichloramate	Ethyl **n**-[1-(2,2,2-trichloro-1-hydroxy-ethyl)] carbamate
E.9	Etryptamine	3-(2-Aminobutyl) indole
E.10	Etymemazine	10-(3-Dimethylamino-2-methylpropyl)-2-ethylphenothiazine
F.1	Fluphenazine	10-[3-[4-(2-Hydroxyethyl)piperazine-1-yl] propyl]-2-trifluoromethylphenothiazine
F.2	Furosemide	4-Chloro-N-furfuryl-5-sulphamoylanthranilic acid: Frusemide (B.A.N.)
17-9-87 | G.1	Glyburide	5-chloro-N-[2-[4-[[[(cyclohexylamino carbonyl]amino]sulfonyl]phenyl]ethyl]-2-methoxy benzamide: 1-4[4-[2-(5-chloro-2-methoxybenzamido)ethyl]phenylsulfonyl]-3-cyclohexylurea: Glibenclamide
H.1	Haloperidol	4-(4-Chlorophenyl)-1-[3-(4-fluorobenzoyl) propyl]-piperidin-4-ol: 4-[4-**p**-Chloro-phenyl)-4-hydroxypiperidino]-4'-fluoro-butyrophenone
H.2	Hydroxychloroquine	7-Chloro-4[4-(N-ethyl-N-2-hydroxyethyl-amino)-1-methylbutyl-amino] quinoline
H.3	Hydroxyzine	1-(**p**-chloro-α-phenylbenzyl)-4-(2-hydroxy ethoxyethyl)piperazine
I.1	Idoxuridine	5-Iodo-2'-deoxyuridine
I.2	Imipramine	5-(3-dimethylaminopropyl)-10,11-dihydro-5H-dibenz[b,f]azepine
I.3	Indomethacin	1-(**p**-Chlorobenzoyl)-5-methoxy-2-methyl-indole-3-acetic acid
I.4	Iproniazid	1-isonicotinoyl-2-isopropylhydrazine
I.5	Isocarboxazid	3-N-Benzylhydrazinocarbonyl-5-methyl-isoxazole
I.6	Isoproterenol	3,4-Dihydroxy-α-[(isopropylamino) methyl] benzyl alcohol: Isoprenaline
L.1	Liothyronine	L-α-Amino-3-[(4-hydroxy-3-iodophenoxy) -3,5-di-iodo-phenyl] propionic acid

*(R) Minor correction

TABLE -- Continued

Item No.	Proper Names	Chemical Names and Synonyms
M.1	Mefenamic acid	N-(2,3-Xylyl)-anthranilic acid
M.2	Melphalan	4-Di-(2-chloroethyl)amino-L-phenylalanine
M.3	Mepazine	10-[(1-methyl-3-piperidyl) methyl] phenothiazine
M.4	Mephenesin	3-**o**-toloxy-1,2-propanediol
M.5	Mephenoxalone	5-(**o**-Methoxyphenoxymethyl)-2-oxazolidinone
M.6	Meprobamate	2,2-di(carbamoylmethyl) pentane
M.7	Methaqualone	2-Methyl-3-**o**-tolyquinazolin-4-one: 2-Methyl-3-**o**-tolyl-4-quinazolone
M.8	Methisazone	1-Methylindoline-2,3-dione-3-thiosemicarbazone: N-Methylisatin-β-thiosemicarbazone
M.9	Methotrimeprazine	10-[3-(2-Methyl)dimethylamino propyl]-2-methoxyphenothiazine: Levomepromazine
M.10	Methyldopa	1-3-(3,4-Dihydroxyphenyl)-2-methylalanine
M.11	Methylparafynol	3-methyl-1-pentyn-3-ol: Methylpentynol
M.12	Methylphenidate	Methyl-1-phenyl-1-(2-piperidyl) acetate
M.13	Methyprylon	3,3-diethyl-5-methyl-2,4-piperidinedione
M.14	Methysergide	1-(Hydroxymethyl)propylamide of 1-methyl-*d*-lysergic acid
M.15	Metyrapone	2-Methyl-1,2-di(3-pyridyl)propan-1-one
N.1	Nalidixic Acid	1-Ethyl-7-methyl-4-oxo-1,8-naphthyridine-3-carboxylic acid
N.2	Nialamide	1-[2-(benzycarbamyl)ethyl]-2-isonicotinoylhydrazine
N.3	Nortriptyline	3-(3-Methylaminopropylidene)-1,2,4,5-dibenzocycloheptа-1,4-diene
O.1	Oxanimide	2-ethyl-3-propyl-glycidamide
O.2	Oxazepam	7-Chloro-1,3-dihydro-3-hydroxy-5-phenyl-1,4-benzodiazepin-2-one
O.3	Oxyphenbutazone	4-**n**-Butyl-2-(4-hydroxyphenyl)-1-phenyl-pyrazolidine-3,5-dione
P.1	Paramethadione	3,5-dimethyl-5-ethyl-2,4-oxazolidinedione
P.2	Pargyline	N-Benzyl-N-methylprop-2-ynylamine
P.3	Pemoline	2-Imino-5-phenyloxazolidin-4-one
P.4	Pentazocine	1,2,3,4,5,6-Hexahydro-8-hydroxy-6,11-dimethyl-3-(3-methylbut-2-enyl)-2,6-methano-3-benzazocine: 1,2,3,4,5,6-Hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-2,6-methano-3-benzazocin-8-ol
P.5	Pentolinium Tartrate	NN'-Pentamethylenedi-(methylpyrrolidinium hydrogen tartrate)
P.6	Perphenazine	2-chloro-10-[3-[1-(2-hydroxyethyl)-4-piperazinyl]propyl] phenothiazine
P.7	Phacetoperane	*l*-1-Phenyl-1-(2'-piperidyl)-1-acetoxy-methane
P.8	Phenacemide	(Phenylacetyl)urea
P.9	Phenacetin	**p**-acetphenetidin: Acetphenetidin: Acetophenetidin: **p**-ethoxyacetanilid
P.10	Phenaglycodol	2-**p**-chlorophenyl-3-methyl-2,3-butanediol
P.11	Phendimetrazine	3,4-Dimethyl-2 Phenylmorpholine
P.12	Phenelzine	2-phenylethylhydrazine
P.13	Phenformin	N'-β-phenethylformamidinyliminourea
P.14	Phenіprazine	α-Methylphenethylhydrazine
P.15	Phenmetrazine	Tetrahydro-3-methyl-2-phenyl-1,4-oxazine: 3-methyl-2-phenylmorpholine
P.16	Phentermine	α,α-Dimethylphenethylamine: phenyl-tert-butylamine
P.17	Phenylindanedione	2-phenylindane-1,3-dione

*(R) Minor correction

Item No.	Proper Names	Chemical Names and Synonyms
P.18	Phenyltoloxamine	N,N-dimethyl-2-(a-phenyl-o-tolyloxy) ethylamine
P.19	Pholedrine	**p**-(4-hydroxyphenyl)-isopropylmethylamine
P.20	Piperliate	1-piperidine-ethanol benzilate
P.21	Pipradrol	Diphenyl-2-piperidylmethanol
P.22	Prochlorperazine	2-Chloro-10-[3-(1-methyl-4-piperazinyl) propyl] phenothiazine
P.23	Prodilidine	1,2-Dimethyl-3-phenyl-3-pyrrolidinyl propionate
P.24	Propranolol	1-(Isopropylamino)-3-(1-naphthyloxy)-2-propanol
P.25	Prothipendyl	9-(3-Dimethylaminopropyl)-10-thia-1,9-diaza-anthracene
P.26	Protriptyline	7-(3-Methylaminopropyl)-1,2:5,6-dibenzo-cycloheptatrien: N-Methyl-5H-dibenzo [a,d] cycloheptene-5-propylamine
P.27	Pyrazinamide	Pyrazinoic acid amide
R.1	Rifampin	3-[[(4-methyl-1-piperazinyl)imino]methyl] rifamycin SV: Rifampicin (I.N.N.) (Rifamycin SV is an antibiotic produced by *Streptomyces mediterranci*)
S.01	Sodium Cromoglycate	4H-1-Benzopyran-2-carboxylic acid,5,5'-[(2-hydroxy-1,3-propanediyl) bis(oxy)] bis [4-oxo,disodium salt]: Disodium 5,5'-(2-hydroxytrimethylenedioxy) bis[4-oxo-4H-1-benzopyran-2-carboxylate]: Disodium 4,4'-dioxo-5,5'-(2-hydroxytrimethylene-dioxy)di (chromene-2-carboxylate): Cromolyn Sodium (USP): Disodium Cromoglycate
S.1	Sulfameter	2-(4-Aminobenzenesulphonamido)-5-methoxy-pyrimidine: N'-(5-methoxy-2-pyrimidinyl) sulfanilamide: Sulfamethoxydiazine (B.A.N.)
S.2	Sulfamethazine	N'-(4,6-dimethyl-2-pyrimidyl)sulfanilamide: 2-(**p**-aminobenzenesuylphonamide)-4,6-dimethylpyrimidine: sulphadimedine
S.3	Sulfinpyrazone	1,2-diphenyl-4-(2-phenylsulfinilethyl)-3,5-pyrazolidinedione
S.4	Sulfisoxazole	3,4-dimethyl-5-sulfanilamidoisoxazole: Sulphafurazole
T.1	Tetracaine	2-dimethylaminoethyl-**p**-**n**-butylamino-benzoate: Amethocaine
T.2	Thiethylperazine	2-Ethylthio-10-[3-(4-methylpiperazin-1-yl) propyl]phenothiazine
T.3	Thiopropazate	2-chloro-10-[3-[1-(2-acetoxyethyl)-4-piperazinyl]propyl]phenothiazine
T.4	Thioproperazine	2-Dimethylsulphamoyl-10-[3-(4-methyl-piperazin-1-yl)propyl]phenothiazine
T.5	Thioridazine	10-[2-[2-(1-methylpiperidyl)] ethyl]-2-methylthiophenothiazine
T.6	Tranylcypromine	*Trans d,* 1-2-phenylcyclopropylamine
T.7	Triamterene	2,4,7-Triamino-6-phenylpteridine
T.8	Triflupromazine	10-(3-dimethylaminopropyl)-2-trifluoro-methylphenothiazine: Fluopremazine
T.9	Trimeprazine	10-(3-dimethylamino-2-methylpropyl) phenothiazine
T.10	Trimethadione	3,5,5-trimethyl-2,4-oxazolidinedione: Troxidone

17-3-88

*(R) Minor correction

TABLE -- Concluded

Item No.	Proper Names	Chemical Names and Synonyms
T.11	Trimipramine	5-(3-Dimethylamino-2-methylpropyl)-10,11-dihydro-5H-dibenz[b,f]azepine: 5-(3'-Dimethylamino-2'-methylpropyl)iminodibenzyl
T.12	Tybamate	2-Methyl-2-propyltrimethylene butylcarbamate carbamate: 2-(Hydroxymethyl)-2-methylpentyl butylcarbamate carbamate
V.1	Vinblastine	An alkaloid derived from *Vinca rosea*
V.2	Vincristine	An alkaloid derived from *Vinca rosea*

10-7-80 **C.01.003.** No person shall sell a drug that is not labelled as required by these Regulations.

C.01.004. (1) The inner and outer labels of a drug shall show

17-5-01 (a) on the principal display panel

20-4-93 (i) the proper name, if any, of the drug which, if there is a brand name for the drug, shall immediately precede or follow the brand name in type not less than one-half the size of that of the brand name,

(ii) if there is no proper name, the common name of the drug,

(iii) where a standard for the drug is prescribed in Division 6 of this Part, a statement that the drug is a Canadian Standard Drug, for which the abbreviation C.S.D. may be used,

28-8-90 (iv) where a standard for the drug is not prescribed in Division 6 of this Part but is contained in a publication mentioned in Schedule B to the Act, the name of the publication containing the standard used or its abbreviation as provided in Schedule B or, if a manufacturer's standard is used, a statement setting forth the fact that such a standard is used, and

(v) in both official languages, the notation "sterile" "*stérile*" if the drug is required to be sterile by these Regulations;

17-5-01 (b) on the upper left quarter of the principal display panel

10-7-80 (i) the symbol " Rx " in the case of a drug required by this Part or Part D to be sold on prescription, but in no other case shall the symbol " Rx " appear on the label of a drug,

20-11-97 (ii) the symbol " ◇C◇ " in a clear manner and a conspicuous colour and size, in the case of a controlled drug, other than a controlled drug contained in an agricultural implant and set out in Part III of the schedule to Part G, and

14-5-97 (iii) the symbol " **N** " in a colour contrasting with the rest of the label or in type not less than half the size of any letters used thereon, in the case of a narcotic as defined in the *Narcotic Control Regulations*; and

1-6-00 (iv) in the case of a targeted substance as defined in subsection 1(1) of the *Benzodiazepines and Other Targeted Substances Regulations*, the following symbol in a colour contrasting with the rest of the label and in type not less than half the size of any other letter used on the main panel, namely,



(c) on any panel

(i) the name and address of the manufacturer of the drug,

10-7-80 (ii) the lot number of the drug,

(iii) adequate directions for use of the drug,

(iv) a quantitative list of the medicinal ingredients of the drug by their proper names or, if they have no proper names, by their common names, and

19-11-92 (v) the expiration date of the drug.

(2) In addition to the requirements of subsection (1), the outer label of a drug shall show

(a) the net amount of the drug in the container in terms of weight, measure or number;

(b) in the case of a drug intended for parenteral use, a quantitative list of any preservatives present therein by their proper names or, if they have no proper names, by their common names; and

28-4-89 (c) in the case of a drug for human use that contains mercury or a salt or derivative thereof as a preservative, a quantitative list of all mercurial preservatives present therein by their proper names or, if they have no proper names, by their common names.

5-4-90 (3) Where the container of a drug is too small to accommodate an inner label that conforms to the requirements of these Regulations, the inner label requirements of these Regulations do not apply to the drug in that container if

(a) there is an outer label that complies with the labelling requirements of these Regulations; and
(b) the inner label shows
20-4-93 (i) the proper name of the drug, the common name of the drug if there is no proper name or, in the case of a drug with more than one medicinal ingredient, the brand name of the drug,
23-4-81 (ii) the potency of the drug except where, in the case of a drug with more than one medicinal ingredient, the name used pursuant to subparagraph (i) for that drug is unique for a particular potency of the drug,
(iii) the net contents of the drug if it is not in a discrete dosage form,
(iv) the route of administration of the drug if other than oral,
(v) the lot number of the drug,
(vi) the name of the manufacturer of the drug,
19-11-92 (vii) the expiration date of the drug, and
(viii) the identification of special characteristics of the dosage form if they are not evident from the name of the drug under subparagraphs (i) or (ii).

19-11-92 (4) Revoked by P.C. 1992-2327 of November 19, 1992.

(5) This section does not apply to

(a) a drug sold to a drug manufacturer; or
(b) a drug dispensed pursuant to a prescription, if its label carries suitable directions for use and complies with the requirements of section C.01.005.

C.01.004.1 (1) No person shall import a drug in dosage form into Canada for the purpose of sale unless they have in Canada a person who is responsible for the sale of the drug.
19-12-96

(2) No person who imports a drug in dosage form into Canada shall sell any lot or batch of the drug unless the name of the person who imports it, and the address of the principal place of business in Canada of the person responsible for its sale, appears on the inner and outer labels of the drug.

17-5-01 **C.01.005.** (1) The principal display panel of both the inner label and outer label of a drug sold in dosage form shall show in a clear and legible manner the drug identification number assigned by the Director for that drug pursuant to subsection C.01.014.2(1), preceded by the words "Drug Identification Number" or "Drogue : identification numérique" or both, or the letters "DIN".

26-8-98 *Note:* A manufacturer may, until September 30, 2000, label a drug with the label that was in use on September 30, 1998.

24-4-75 (a) where the drug is not a proprietary medicine as defined in subsection C.10.001 (1), by the word "Drug Identification Number" or "drogue: identification numérique" or both, or their abbreviation "DIN"; or
3-2-76 (b) where the drug is a proprietary medicine as defined by subsection C.10.001(1), by the letters "GP"

(2) Subsection (1) does not apply to a drug

(a) compounded by a pharmacist pursuant to a prescription or by a practitioner; or
4-10-73 (b) sold pursuant to a prescription, where the label of that drug indicates:
20-4-93 (i) the proper name, the common name or the brand name of the drug,
(ii) the potency of the drug; and
(iii) the name of the manufacturer of the drug.

19-3-81 (3) For the purposes of this section and section C.01.014, "a drug in dosage form" means a drug in a form in which it is ready for use by the consumer without requiring any further manufacturing.

C.01.006. Where a package of a drug has only one label, that label shall contain all the information required by these regulations to be shown on both the inner and the outer labels.

C.01.007. No reference, direct or indirect, to the Act or to these regulations shall be made upon any label of or in any advertisement for a drug unless such reference is a specific requirement of the Act or these regulations.

C.01.008. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.009. Where by any statute of the Parliament of Canada or any regulation made thereunder a standard or grade is prescribed for a drug and that standard is given a name or designation by such statute or regulation, no person shall on a label of or in any advertisement for that drug use that name or designation unless the drug conforms with the standard or grade.

15-6-67 **C.01.010.** Where it is necessary to provide adequate directions for the safe use of a parenteral drug or SCHEDULE F drug that is used in the treatment or prevention of any disease, disorder or abnormal physical state mentioned in SCHEDULE A to the Act, such diseases, disorders or abnormal physical states may be mentioned on the labels and inserts accompanying that drug and to such extent, that drug is hereby exempted from the provisions of section 3 of the Act.

19-11-68 **C.01.011.** (1) A drug referred to in subsection (2) of section 10 of the Act shall be exempt from the standard for any drug contained in any publication mentioned in Schedule B to the Act to the extent that such drug differs from that standard with respect to colour, flavour, shape and size, if such difference does not interfere with any method of assay prescribed in any such publication.

11-5-93 (2) Revoked by P.C. 1993-940 of May 11, 1993.

(3) Where a manufacturer's standard is used for a drug, the manufacturer shall make available to the Director, on request, details of that standard and of method of analysis for the drug acceptable to the Director.

19-11-68 (4) No person shall use a manufacturer's standard for a drug that provides

(a) a lesser degree of purity than the highest degree of purity;
(b) a greater variation in potency than the least variation in potency,
provided for that drug in any publication mentioned in Schedule B to the Act.

C.01.012. A manufacturer who makes representations on a label of a drug in oral dosage form, or in any advertisement, with respect to the site, rate or extent of release to the body of a medicinal ingredient of the drug, or the availability to the body of a medicinal ingredient of the drug, shall

13-1-94

(a) before making the representations, conduct such investigations, using an acceptable method, as may be necessary to demonstrate that the site, rate or extent of release to the body of the medicinal ingredient of the drug and the availability to the body of the medicinal ingredient of the drug, correspond to the representations; and

28-2-64 (b) on request submit the record of such investigations to the Director.

C.01.013. (1) Where the manufacturer of a drug is requested in writing by the Director to submit on or before a specified day evidence with respect to a drug, the manufacturer shall make no further sales of that drug after that day unless he has submitted the evidence requested.

(2) Where the Director is of the opinion that the evidence submitted by a manufacturer, pursuant to subsection (1), is not sufficient, he shall notify the manufacturer in writing that the evidence is not sufficient.

23-6-71 (3) Where, pursuant to subsection (2), a manufacturer is notified that the evidence with respect to a drug is not sufficient, he shall make no further sales of that drug unless he submits further evidence and is notified in writing by the Director that further evidence is sufficient.

(4) A reference in this section to evidence with respect to a drug means evidence to establish the safety of the drug under the conditions of use recommended and the effectiveness of the drug for the purposes recommended.

Assignment and Cancellation of Drug Identification Numbers

C.01.014. (1) No manufacturer shall sell a drug in dosage form unless a drug identification number has been assigned for that drug and the assignment of the number has not been cancelled pursuant to section C.01.014.6.

19-12-96 (2) Subsection (1) does not apply in respect of a drug listed in Schedule C to the Act, whole blood and its components, or a medicated feed as defined in section 2 of the *Feeds Regulations, 1983*.

C.01.014.1 (1) A manufacturer of a drug, a person authorized by a manufacturer or, in the case of a drug to be imported into Canada, the importer of the drug may make an application for a drug identification number for that drug

19-3-81 (2) An application under subsection (1) shall be made to the Director in writing and shall set out the following information:

(a) the name of the manufacturer of the drug as it will appear on the label;
(b) the pharmaceutical form in which the drug is to be sold;
(c) in the case of any drug other than a drug described in paragraph (d), the recommended route of administration;
(d) in the case of a drug for disinfection in premises, the types of premises for which its use is recommended;
(e) a quantitative list of the medicinal ingredients contained in the drug by their proper names or, if they have no proper names, by their common names;
20-4-93 (f) the brand name under which the drug is to be sold;
(g) whether the drug is for human use, veterinary use or disinfection in premises;
(h) the name and quantity of each colouring ingredient that is not a medicinal ingredient;
(i) the use or purpose for which the drug is recommended;
(j) the recommended dosage of the drug;
19-3-81 (k) the address of the manufacturer referred to in paragraph (a) and, where the address is outside the country, the name and address of the importer of the drug;
(l) the name and address of any individual, firm, partnership, or corporation, other than the names and addresses referred to in paragraphs (a) and (k), that will appear on the label of the drug;
(m) the written text of all labels and package inserts to be used in connection with the drug and of any further prescribing information stated to be available on request; and
(n) the name and position of the person who signed the application and the date of signature.

26-8-98 (3) In the case of a new drug, a new drug submission or an abbreviated new drug submission filed pursuant to section C.08.002 or C.08.002.1 shall be regarded as an application for a drug identification number.

C.01.014.2 (1) Subject to subsection (2), if a manufacturer or importer has provided all the information described in subsection C.01.014.1(2) or section C.08.002 or C.08.002.1, as the case may be, in respect of a drug, the Director shall issue to the manufacturer or importer a document that

26-8-98 (a) sets out

(i) the drug identification number assigned for the drug, preceded by the letters "DIN", or

(ii) if there are two or more brand names for the drug, the drug identification numbers assigned by the Director for the drug, each of which pertains to one of the brand names and is preceded by the letters "DIN"; and

(b) contains the information referred to in paragraphs C.01.014.1(2)(a) to (f).

(2) Where the Director believes on reasonable grounds that a product in respect of which an application referred to in section C.01.014.1 has been made

(a) is not a drug, or

(b) is a drug but that its sale would cause injury to the health of the consumer or purchaser or would be a violation of the Act or these Regulations,

he may refuse to issue the document referred to in subsection (1).

(3) Where the Director, pursuant to subsection (2), refuses to issue the document, the applicant may submit additional information and request the Director to reconsider his decision.

19-3-81 (4) On the basis of the additional information submitted pursuant to subsection (3), the Director shall reconsider the grounds on which the refusal to issue the document was made.

26-8-98 **C.01.014.3** The manufacturer or importer or person authorized by the manufacturer or importer shall, within 30 days after commencing sale of a drug, date and sign the document issued pursuant to subsection C.01.014.2(1) in respect of the drug and return the document

(a) with a confirmation that the information recorded therein is correct;

(b) indicating the date on which the drug was first sold in Canada; and

(c) accompanied by samples or facsimiles of all labels and package inserts and any further prescribing information stated to be available on request.

26-8-98 **C.01.014.4** If the information referred to in subsection C.01.014.1(2) in respect of a drug is no longer correct owing to a change in the subject matter of the information,

30-4-92 (a) in the case of a change in the subject matter of any of the information referred to in paragraphs C.01.014.1(2)(a) to (f)

(i) that occurs prior to the sale of the drug, a new application shall be made, or

(ii) that occurs after the sale of the drug, no further sale of the drug shall be made until a new application for a drug identification number in respect of that drug is made and a number is assigned; and

30-4-92 (b) in the case of a change in the subject matter of any of the information referred to in paragraphs C.01.014.1(2)(g) to (k)

(i) that occurs prior to the sale of the drug, the particulars of the change shall be submitted with the return of the document referred to in section C.01.014.3, or

(ii) that occurs after the sale of the drug, the person to whom the drug identification number in respect of that drug was issued shall, within 30 days of the change, inform the Director of the change.

C.01.014.5 Every manufacturer of a drug shall, annually before the first day of October and in a form authorized by the Director, furnish the Director with a notification signed by the manufacturer or by a person authorized to sign on his behalf, confirming that all the information previously supplied by the manufacturer with respect to that drug is correct.

C.01.014.6 (1) The Director shall cancel the assignment of a drug identification number for a drug where

(a) the person to whom the number was assigned advises that the sale or import of the drug has been discontinued;

(b) the drug is a new drug in respect of which the notice of compliance has been suspended pursuant to section C.08.006; or

(c) it has been determined that the product in respect of which the number was assigned is not a drug.

(2) The Director may cancel the assignment of a drug identification number for a drug where

(a) the manufacturer of the drug has failed to comply with section C.01.014.5; or
19-3-81 (b) the manufacturer to whom the number was assigned has been notified pursuant to section C.01.013 that the evidence he submitted in respect of the drug is insufficient.

C.01.014.7 Where a person who has been assigned a drug identification number for a drug discontinues sale of the drug in Canada, he shall, within 30 days of such discontinuation, inform the Director that he is no longer selling the drug.

Tablet Disintegration Times

C.01.015. (1) Subject to subsection (2), no person shall sell for human use a drug in the form of a tablet that is intended to be swallowed whole unless, when tested by the official method DO-25, Determination of the Disintegration Time of Tablets, dated July 5, 1989,

(a) in the case of an uncoated tablet, the tablet disintegrates in not more than 45 minutes;
(b) in the case of a plain coated tablet, the tablet disintegrates in not more than 60 minutes; and
(c) in the case where the label of the drug indicates that the tablet carries an enteric coating or a coating designed to serve a purpose similar to that of an enteric coating, the tablet does not disintegrate when exposed for 60 minutes to simulated gastric fluid, but when it is subsequently exposed for a continuous period to simulated intestinal fluid the tablet disintegrates in not more than 60 minutes.

(2) Subsection (1) does not apply in respect of a drug in the form of a tablet where

21-9-89
(a) a notice of compliance in respect of the drug in the form of a tablet has been issued pursuant to section C.08.004;
26-8-98 (b) Repealed by P.C. 1998-1461 of August 26, 1998.
21-9-89 (c) a dissolution or disintegration test for the drug in the form of a tablet is prescribed in Division 6 of this Part;
(d) the drug is labelled as complying with a standard contained in a publication referred to in Schedule B to the Act;
(e) the drug has been demonstrated by an acceptable method to be available to the body; or
13-1-94 (f) representations regarding the drug are made on its label, or in any advertisement, with respect to the site, rate or extent of release to the body of a medicinal ingredient of that drug, or the availability to the body of a medicinal ingredient of that drug.

Adverse Drug Reaction Reporting

C.01.016. (1) No manufacturer shall sell a drug unless the manufacturer, with respect to any adverse drug reaction or any serious adverse drug reaction known to the manufacturer that occurs after this section comes into force, furnishes to the Director

(a) a report of all information in respect of any serious adverse drug reaction that has occurred in Canada with respect to the drug, within 15 days after receiving the information; and
(b) a report of all information in respect of any serious unexpected adverse drug reaction that has occurred outside Canada with respect to the drug, within 15 days after receiving the information.

(2) The manufacturer shall, on an annual basis and whenever requested to do so by the Director, conduct a concise, critical analysis of the adverse drug reactions and serious adverse drug reactions to a drug referred to in subsection (1) and prepare a summary report in respect of the reports received during the previous twelve months or received during such period of time as the Director may specify.

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(3) Where, after reviewing any report furnished pursuant to subsection (1) and any available safety data relating to the drug, the Director considers that the drug may not be safe when used under the recommended conditions of use, the Director may, for the purpose of assessing the safety of the drug, request in writing, that the manufacturer submit

(a) case reports of all adverse drug reactions and serious adverse drug reactions to that drug that are known to the manufacturer; and
(b) a summary report prepared pursuant to subsection (2).

(4) The manufacturer shall submit the case reports and summary report referred to in subsection (3) within 30 days after receiving the request from the Director.

7-11-95 **C.01.017.** The manufacturer shall maintain records of the reports and case reports referred to in section C.01.016 for auditing purposes.

Limits of Drug Dosage

2-2-84 **C.01.021.** Except as provided in these Regulations, no person shall sell a drug for human use listed in the following table unless both the inner and outer labels other than the inner label of a single dose container carry a statement of

(a) the quantitative content of the drug, and
(b) the recommended single and daily adult dose designated as such, except for
  (i) preparations solely for external use, or
  (ii) preparations solely for children's use, and
(c) adequate directions for use when the drug is recommended for children which shall be either
  (i) the statement, "CHILDREN: As directed by the physician", or
  (ii) a suitably reduced maximum single and daily dose which shall not exceed the following:

Age in years	*Proportion of adult dose*
10-14	one-half
5-9	one-fourth
2-4	one-sixth
under 2 years	as directed by physician.

TABLE OF LIMITS OF DRUG DOSAGE FOR ADULTS

	Item	External Use --- Maximum Limit	Internal Use --- Maximum Dosage Unless otherwise stated, doses are in milligrams	
		Per cent	Single	Daily
14-1-88	Acetaminophen	--	650.0	4.0g
2-1-58	Acetanilide and derivatives (except N-Acetyl-p-aminophenol)	--	65.0	195.0
2-2-84	Acetylsalicylic acid	--	650.0	4.0g
	Revoked by P.C. 1984-337 of February 2, 1984			
	Aconitine, its preparations and derivatives	0.02	0.1	0.1
	Adonis vernalis	--	65.0	195.0
	Amylocaine, its salts and derivates when sold or recommended for ophthalmic use	0.0	0.0	0.0
24-7-85	Amylocaine Hydrochloride, except when sold or recommended for ophthalmic use	1.0	0.0	0.0
	Antimony, compounds of	--	3.3	13.0
28-4-89	Delete by P.C. 1989-719 of April 28, 1989 - shall come to force on January 1, 1990			
	Atropine, Methylatropine, and their salts	1.0	0.13	0.44
	Belladonna and its preparations, on the basis of belladonna alkaloids	0.375	0.13	0.44
	Benzene (Benzol)	--	--	--
	Benzocaine	8.0	195.0	585.0
	Beta-Naphthol	--	195.0	585.0
	Revoked by P.C. 1980-1850 of July 10, 1980			
	Butacaine, its salts and derivatives when sold or recommended for ophthalmic use	0.0	0.0	0.0
	Butacaine Sulphate, except when sold or recommended for ophthalmic use	1.0	0.0	0.0
24-7-85	Cadexomer Iodine	0.0	0.0	0.0
	Cantharides, cantharidin, and their preparations, on the basis of cantharidin, except blisters	0.03	0.0	0.0
	Cantharides, blisters only	0.2	0.0	0.0
	Cedar Oil	25.0	0.0	0.0
	Revoked by P.C. 1980-1850 of July 10, 1980			
	Chlorbutol (not more often than every 4 hours)	--	325.0	975.0
2-2-84	Choline Salicylate	--	870.0	5.22g
24-7-85	Cinchocaine Hydrochloride, except suppositories	1.0	0.0	0.0
	Cinchocaine Hydrochloride, suppositories only	--	11.0	11.0
	Colchicine and its salts	--	0.55	1.65
	Colchicum and its preparations, on the basis of colchicine	--	0.27	0.81
	Croton Oil	10.0	0.0	0.0
28-4-89	Delete by P.C. 1989-719 of April 28, 1989 - shall come to force on January 1, 1990			
4-5-78	Revoked by P.C. 1978-1515 of May 4, 1978			
13-8-69	Cyproheptadine and its salts when sold or recommended for the promotion of weight gain	--	0.0	0.0
	Ephedrine and its salts	--	11.0	32.5
	Ephedrine and its salts, sprays	1.0	--	--
	Epinephrine and its salts, sprays	1.0	--	--
	Revoked by P.C. 1980-1850 of July 10, 1980			
	Gelseminine (Gelsemine) and its salts (not to be repeated within 4 hours)	--	0.55	1.65
	Gelsemium and its preparations, on the basis of the crude drug	--	16.2	48.6
	Hydrocyanic (Prussic) Acid as 2 per cent solution	--	0.062ml	0.31ml
23-11-89	Hydroquinone	2.0	--	--
	Hyoscine (Scopolamine) and its salts	0.5	0.325	0.975
	Hyoscine aminoxide hydrobromide	0.5	0.325	0.975
	Hyoscyamine and its salts	--	0.325	0.975
28-4-89	Hyoscyamus and its preparations, on the basis of hyoscyamus alkaloids	--	0.073	0.22
	Delete by P.C. 1989-719 of April 28, 1989 - shall come to force on January 1, 1990			

*(R) Minor correction

	Item	External Use --- Maximum Limit	Internal Use --- Maximum Dosage Unless otherwise stated, doses are in milligrams	
		Per cent	Single	Daily
	Lobelia and its preparations, on the basis of the crude drug	--	130.0	390.0
18-9-58	Lobeline and its salts	--	2.0	6.0
2-2-84	Magnesium Salicylate	--	650.0	4.0g
28-4-89	Delete by P.C. 1989-719 of April 28, 1989 - shall come to force January 1, 1990			
2-2-84	Methyl Salicylate	30.0	--	--
	Methylene Blue	--	130.0	390.0
	Revoked by P.C. 1980-1850 of July 10, 1980			
28-4-89	Delete by P.C. 1989-719 of April 28, 1989 - shall come to force January 1, 1990			
	Phenacetin	--	650.0	1.95gm
18-2-66	Phenazone and compounds thereof	--	325.0	975.0
	Phenol	2.0	32.5	260.0
18-9-58	Phenylpropanolamine when sold or recommended as an appetite depressant	--	0.0	0.0
	Phosphorus	--	0.0	0.0
28-2-64	Podophyllin	0.0	0.0	0.0
	Potassium Chlorate	--	325.0	975.0
	Potassium Chlorate, gargle	2.5	--	--
	Procaine and its salts	--	--	--
24-7-85	Proxymetacaine, its salts and derivatives when sold or recommended for ophthalmic use	0.0	0.0	0.0
28-4-89	Delete by P.C. 1989-719 of April 28, 1989 - shall come to force January 1, 1990			
	Revoked by P.C. 1984-337 of February 2, 1984			
	Salicylamide	--	975.0	2.925gm
	Santonin	--	65.0	130.0
26-6-76	Selenium and its compounds	2.5	0.0	0.0
28-4-89	Delete by P.C. 1989-719 of April 28, 1989 - shall come to force January 1, 1990			
	Delete by P.C. 1989-719 of April 28, 1989 - shall come to force January 1, 1990			
	Sodium Chlorate	--	325.0	975.0
16-7-59	Sodium Fluoride	--	0.1	0.1
28-4-89	Delete by P.C. 1989-719 of April 28, 1989 - shall come to force January 1, 1990			
2-2-84	Sodium Salicylate	--	650.0	4.0g
	Squill and its preparations, on the basis of the crude drug	--	32.5	97.5
	Stramonium and its preparations, on the basis of stramonium alkaloids	--	0.16	0.65
1-10-68	Strychnine and its salts	--	0.0	0.0
29-6-76	Tannic Acid	--	150.0	1000.0
24-7-85	Tetracaine, its salts and derivatives when sold or recommended for ophthalmic use	0.0	0.0	0.0
16-7-59	Thiocyanates	0.0	0.0	0.0
	Urethane	0.0	0.0	0.0

Where drugs having similar physiological actions occur in combination, the dosage of each shall be proportionately reduced.

Accurate dosages may be expressed in either metric units or imperial units. If the dosage is expressed in both systems, then an approximation may be used for one expression, but such approximation must precede or follow the accurate statement by which the product will be judged and must be in brackets.

C.01.022. Notwithstanding C.01.021 (b), the recommended single and daily dosage of a drug

(a) intended to be burned and the smoke inhaled may be increased to ten times the oral dose, and
(b) intended for use as suppositories may be increased to 33 1/3 per cent in excess of the oral dose.

2-2-84

C.01.024. (1) Sections C.01.021 and C.01.022 do not apply to

(a) a drug sold to a drug manufacturer; or
(b) a drug sold on prescription.

(2) Paragraph C.01.021 (c) does not apply to

(a) acetaminophen;
(b) acetylsalicylic acid;
(c) magnesium salicylate;
(d) sodium salicylate; or
(e) choline salicylate.

(3) Where a drug mentioned in any of paragraphs (2)(a) to (d) is recommended for children, no person shall sell the drug for human use unless both the inner and the outer labels carry a statement that it is recommended

(a) that the drug be used as directed by a physician; or
(b) that the maximum doses of the drug not exceed the amounts set out in the following table and that single doses not be administered more frequently than every four hours.

TABLE

MAXIMUM DOSE

28-8-90

Item	*Column I* *Age*	*Column II* *Maximum Children's Dose (80 mg units) Acetaminophen Drops*	*Column III* *Maximum Children's Dose (80 mg units)*	*Column IV* *Maximum Children's Dose (160 mg units Acetaminophen*	*Column V* *Maximum Adults Dose (325 mg units*	*Column VI* *Maximum Single Dose (mg)*	*Column VII* *Maximum Daily Dose (mg)*
1.	11 to under 12 years	--	6	3	1.5	480	2400
2.	9 to under 11 years	--	5	2.5	1.25	400	2000
3.	6 to under 9 years	--	4	2	1	320	1600
4.	4 to under 6 years	--	3	1.5	--	240	1200
5.	2 to under 4 years	--	2	1	--	160	800
6.	1 to under 2 years	1.5 or as directed by a physician	--	--	--	120	600
7.	4 months to under 1 year	1 or as directed by a physician	--	--	--	80	400
8.	0 to under 4 months	0.5 or as directed by a physician	--	--	--	40	200

*(R) Minor correction

(4) Where choline salicylate is recommended for children, no person shall sell the drug for human use unless both the inner and the outer labels carry a statement that it is recommended

(a) that the drug be used as directed by a physician; or
(b) that the maximum doses of the drug not exceed the amounts set out in the following table and that single doses not be administered more frequently than every four hours.

2-2-84

TABLE

MAXIMUM DOSE

Age (Years)	*Adult Dosage Units (435 mg)*	*Single Dose (mg)*	*Maximum Daily Dose (mg)*
11 to under 12	1 1/2	660	3 300
9 to under 11	1 1/4	550	2 750
6 to under 9	1	440	2 200
4 to under 6	3/4	330	1 650
2 to under 4	1/2	220	1 100
Under 2	As directed by physician		

C.01.025. Both the inner and the outer labels of a drug that carry a recommended single or daily dosage or a statement of concentration in excess of the limits provided by C.01.021 shall carry a caution that the product is to be used only on the advice of a physician.

C.01.026. The provisions of C.01.025 do not apply to

(a) a drug sold on prescription, or
(b) the inner label of a single-dose container.

C.01.027. (1) Where a person advertises to the general public a drug for human use, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug if it

(a) contains a drug set out in the table to section C.01.021; and
(b) carries on its label
20-4-93 (i) a statement of the recommended single or daily adult dosage that results in a single or daily adult dosage of the drug referred to in paragraph (a) in excess of the maximum dosage set out in the table to section C.01.021 for that drug, or
(ii) a statement that shows a concentration of the drug referred to in paragraph (a) in excess of the maximum limit set out in the table to section C.01.021 for that drug.

(2) Subsection (1) does not apply to products containing

(a) acetaminophen;
2-6-94 (b) acetylsalicylic acid;
(c) choline salicylate;
(d) magnesium salicylate; or
(e) sodium salicylate.

4-8-93 (3) Where a person advertises to the general public a drug for human use that contains acetylsalicylic acid, the person shall not make any representation with respect to its administration to or use by children or teenagers.

Cautionary Statements and Child Resistant Packages

C.01.028. (1) Subject to subsection (2), the inner and outer labels of a drug that contains

10-1-86 (a) acetylsalicylic acid or any of its salts or derivatives, salicylic acid or a salt thereof, or salicylamide, where the drug is recommended for children, shall carry a cautionary statement to the effect that the drug should not be administered to a child under two years of age except on the advice of a physician;
(b) boric acid or sodium borate as a medicinal ingredient shall carry a cautionary statement to the effect that the drug should not be administered to a child under three years of age;
(c) hyoscine (scopolamine) or a salt thereof shall carry a cautionary statement to the effect that the drug should not be used by persons suffering from glaucoma or where it causes blurring of the vision or pressure pain within the eye;
4-8-93 (d) phenacetin, either singly or in combination with other drugs, shall carry the following cautionary statement: "CAUTION: May be injurious if taken in large doses or for a long time. Do not exceed the recommended dose without consulting a physician"; or
(e) acetylsalicylic acid for internal use shall carry a cautionary statement to the effect that the drug should not be administered to or used by children or teenagers who have chicken pox or manifest flu symptoms before a physician or pharmacist is consulted about Reye's syndrome, which statement shall also refer to the fact that Reye's syndrome is a rare and serious illness.

(2) Subsection (1) does not apply to a drug that is

(a) intended for parenteral use only;
10-1-86 (b) dispensed pursuant to a prescription; or
(c) required to be sold on prescription pursuant to these Regulations or pursuant to the Narcotic Control Regulations.

C.01.029. (1) Subject to subsections C.01.031.2(1) and (2), the inner and outer labels of a drug

(a) that contains
  (i) salicylic acid, a salt thereof or salicylamide,
  (ii) acetylsalicylic acid, or any of its salts or derivatives,
10-1-86 (iii) acetaminophen, or
  (iv) more than 5 per cent alkyl salicylates, or
(b) that is in a package that contains
23-9-93 (i) more than the equivalent of 250 mg of elemental iron, or
  (ii) more than the equivalent of 120 mg of fluoride ion, unless the drug is intended solely for use in dentists' offices,

shall carry a cautionary statement to the effect that the drug should be kept out of the reach of children.

(2) Subject to subsections C.01.031.2(1) and (2), the inner and outer labels of a drug that is in a package that contains

28-8-90 (a) more than 1.5 g of salicylic acid or the equivalent quantity of any of its salts or salicylamide,
(b) more than 2 g of acetylsalicylic acid or the equivalent quantity of any of its salts or derivatives,
(c) more than 3.2 g of acetaminophen,
(d) more than the equivalent of 250 mg of elemental iron, or
23-9-93 (e) more than the equivalent of 120 mg of fluoride ion, unless the drug is intended solely for use in dentists' offices,

shall carry a cautionary statement to the effect that there is enough drug in the package to seriously harm a child,

30-7-87 (3) The cautionary statements required under subsections (1) and (2) shall be preceded by a prominently displayed symbol that is octagonal in shape, conspicuous in colour and on a background of a contrasting colour.

5-6-03 **C.01.030.** Repealed by P.C. 2003-847 of June 5, 2003.

C.01.031. (1) Subject to section C.01.031.2,

(a) no person shall sell a drug described in subsection C.01.029(1) unless
  (i) where the drug is recommended solely for children, it is packaged in a child resistant package, or
  (ii) where the drug is not recommended solely for children, at least one of the sizes of packages available for sale is packaged in a child resistant package; and
18-12-86 (b) where a drug described in subsection C.01.029(1) is packaged in a package that is not a child resistant package, the outer label shall carry a statement that the drug is available in a child resistant package.

23-9-93 (2) Revoked by P.C. 1993-1805 of September 30, 1993

30-7-87 **C.01.031.2.** (1) Sections C.01.029 to C.01.031 do not apply to a drug that is

(a) required by these Regulations or the Narcotic Control Regulations to be sold on prescription;
(b) intended for parenteral use only;
10-1-86 (c) in effervescent or powder form;
(d) in suppository form;
(e) intended for topical use, unless it is a liquid preparation containing more than 5 per cent alkyl salicylates;
(f) packaged in a non-reclosable package containing not more than two adult standard dosage units per package, or
23-9-93 (g) in toothpaste form.

(2) Sections C.01.029 to C.01.031 do not apply to a drug that is repackaged by a pharmacist or practitioner at the time of sale.

(3) Section C.01.031 does not apply to a drug that is

(a) sold only in containers that have roll-on or spray applicators or permanently installed wick applicators;
(b) sold for exclusive use in animals other than household pets, or
23-9-93 (c) intended solely for use in dentists' offices, or packaged for hospital use only.

C.01.032. No person shall sell a corticosteroid drug for ophthalmic use unless

28-2-64 (a) the outer label or the package insert carries, as part of the directions for use, the following statements:
"Contraindications
Viral Diseases of the cornea and conjunctiva;
Tuberculosis of the eye;
Fungal disease of the eye;
Acute purulent untreated infections of the eye, which, like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid.
Side Effects
Extended ophthalmic use of corticosteroid drugs may cause increased intraocular pressure in certain individuals and in those diseases causing thinning of the cornea, perforation has been known to occur"; and
18-6-64 (b) the inner label carries the statements required by paragraph (a) or instructions to see the outer label or package insert for information about contraindications and side effects.

C.01.033. Section C.01.032 does not apply to a corticosteroid drug that is dispensed by a registered pharmacist pursuant to a prescription.

28-2-64 **C.01.034.** No person shall disseminate to a practitioner promotional literature about corticosteroid drugs for ophthalmic use unless the statements required by section C.01.032 (a) are included in the literature.

C.01.035. Sections C.01.032 and C.01.034 do not apply to a drug sold solely for veterinary use.

10-1-86 **Miscellaneous**

C.01.036. (1) No manufacturer or importer shall sell

(a) a drug that contains phenacetin in combination with any salt or derivative of salicylic acid;
4-5-78 (b) a drug for human use that contains
(i) oxyphenisatin,
(ii) oxyphenisatin acetate,
(iii) phenisatin, or
(c) a drug for human use that contains mercury or a salt or derivative thereof, unless the drug is
(i) a drug described in Schedule C or D to the Act, or
(ii) one of the following drugs, namely,
(A) an ophthalmic drug or other drug to be used in the area of the eye,
(B) a drug for nasal administration,
(C) a drug for optic administration, or
28-4-89 (D) a drug for parenteral administration that is packaged in a multi-dose container,
in which the mercury or the salt or derivative thereof is present as a preservative and the manufacturer or importer has submitted evidence to the Director demonstrating that the only satisfactory way to maintain the sterility or stability of the drug is to use that preservative.

(2) For the purpose of clause (1)(c)(ii)(A), "area of the eye" means the area bounded by the supraorbital and infraorbital ridges and includes the eyebrows, the skin underlying the eyebrows, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball and the soft tissue that lies below the eye and within the infraorbital ridge.

(3) Subsections (1) and (2) shall come into force on January 1, 1990.

16-11-78 **C.01.036.1.** No person shall sell, or advertise for sale, nitrous oxide to the general public.

C.01.037. (1) No person shall sell to the general public a drug that is recommended solely for children if the package in which the drug is sold contains

16-6-88 (a) more than 1.92 g of salicylamide or salicylic acid or the equivalent quantity of a salt of salicylic acid;
28-8-90 (b) more than 1.92 g of acetylsalicylic acid or the equivalent quantity of a salt or derivative thereof;
(c) more than 3.2 g of acetaminophen in 160 mg dosage units; or
(d) more than 1.92 g of acetaminophen in 80 mg dosage units.

10-1-85 (2) Subsection (1) does not apply to a drug dispensed pursuant to a prescription.

C.01.038. A drug for human use is adulterated if it contains

(a) Strychnine or any of its salts; or
(b) extracts or tinctures of
(i) *Strychnos nux vomica*,
28-6-79 (ii) *Strychnos Ignatii*, or
10-3-88 (iii) a *Strychnos* species containing strychnine, other than those species mentioned in subparagraph (i) and (ii);
(c) Methapyrilene or any of its salts,
(d) Echimidine or any of its salts; or
(e) any of the following plant species or extracts or tinctures thereof:
10-3-88 (i) *Symphytum asperum*,
(ii) *Symphytum x uplandicum*, or
(iii) any other plant species containing echimidine.

19-12-96 **C.01.039.** *In vitro* diagnostic products that are or contain drugs other than drugs listed in Schedule E to the Act, and drugs listed in Schedule D to the Act that are labelled for veterinary use only, are exempt from the application of this Part.

28-4-89 **C.01.040.** No manufacturer or importer shall sell a drug for human use that contains as an ingredient
(a) chloroform; or
(b) arsenic or any of its salts or derivatives.

19-11-92 **C.01.040.1.** No manufacturer shall use methyl salicylate as a medicinal ingredient in a drug for internal use in humans.

Colouring Agents

C.01.040.2. (1) No manufacturer shall use a colouring agent in a drug other than a colouring agent listed in subsections (3) and (4).

(2) No person shall import for sale a drug that contains a colouring agent other than a colouring agent listed in subsections (3) and (4).

(2.1) In subsections (3) and (4),

"C.I. (indication of the number)" means the designation used to identify a colouring agent in the *Colour Index* published by The Society of Dyers and Colourists, as amended from time to time; (*C.I. (indication du numéro)*)
30-8-95 "D & C (indication of the colour and the number)" means the designation used to identify, in accordance with the *Code of Federal Regulations* of the United States, a colouring agent that can be used in the United States in drugs and cosmetics; (*D&C (indication de la couleur et du numéro)*)
"FD & C (indication of the colour and the number)" means the designation used to identify, in accordance with the *Code of Federal Regulations* of the United States, a colouring agent that can be used in the United States in food, drugs and cosmetics. (*FD&C (indication de la couleur et du numéro)*)

(3) The following colouring agents are permitted in drugs for internal and external use, namely,

(a) ACID FUCHSIN D (D&C Red No. 33; C.I. No. 17200),
ALIZARIN CYANINE GREEN F (D&C Green No. 5; C.I. No. 61570),
ALLURA RED AC (FD&C Red No. 40; C.I. No. 16035),
AMARANTH (Delisted FD&C Red No. 2; C.I. No. 16185),
30-8-95 ANTHOCYANIN DERIVED FROM JUICE EXPRESSED FROM FRESH EDIBLE FRUITS OR VEGETABLES,
β-APO-8'-CAROTENAL (C.I. No. 40820),

BRILLIANT BLUE FCF SODIUM SALT (FD&C Blue No. 1; C.I. No. 42090),
BRILLIANT BLUE FCF AMMONIUM SALT (D&C Blue No. 4; C.I. No. 42090),
CANTHAXANTHIN (C.I. No. 40850),
CARAMEL,
CARBON BLACK (C.I. No. 77266),
CARMINE (C.I. No. 75470),
CARMOISINE (Delisted Ext. D&C Red No. 10; C.I. No. 14720),
β-CAROTENE (C.I. No. 40800),
CHLOROPHYLL (C.I. No. 75810),
EOSIN YS ACID FORM (D&C Red No. 21; C.I. No. 45380:2),
EOSIN YS SODIUM SALT (D&C Red No. 22; C.I. No. 45380),
ERYTHROSINE (FD&C Red No. 3; C.I. No. 45430),
FAST GREEN FCF (FD&C Green No. 3; C.I. No. 42053),
FLAMING RED (D&C Red No. 36; C.I. No. 12085),
HELINDONE PINK CN (D&C Red No. 30; C.I. No. 73360),
INDIGO (D&C Blue No. 6; C.I. No. 73000),
INDIGOTINE (FD&C Blue No. 2; C.I. No. 73015),
IRON OXIDES (C.I. Nos. 77489, 77491, 77492, 77499),
LITHOL RUBIN B SODIUM SALT (D&C Red No. 6; C.I. No. 15850),
LITHOL RUBIN B CALCIUM SALT (D&C Red No. 7; C.I. No. 1580:1),
PHLOXINE B ACID FORM (D&C Red No. 27; C.I. No. 45410:1),
PHLOXINE B SODIUM SALT (D&C Red No. 28; C.I. No. 45410),
PONCEAU 4R (C.I. No. 16255),
PONCEAU SX (FD&C No. 4; C.I. No. 14700),
QUINOLINE YELLOW WS (D&C Yellow No. 10; C.I. No. 47005),
RIBOFLAVIN,
SUNSET YELLOW FCF (FD&C Yellow No. 6; C.I. No. 15985),
TARTRAZINE (FD&C Yellow No. 5; C.I. No. 19140),
TITANIUM DIOXIDE (C.I. No. 77891);

(b) preparations made by extending any of the colouring agents listed in paragraph (a) on a substratum of
- (i) alumina,
- (ii) blanc fixe,
- (iii) gloss white,
- (iv) clay,
- (v) zinc oxide,
- (vi) talc,
- (vii) rosin,
- (viii) aluminum benzoate,
- (ix) calcium carbonate, or
- (x) any combination of the substances listed in subparagraphs (i) to (ix); and

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(c) preparations made by extending any sodium, potassium, aluminum, barium, calcium, strontium or zirconium salt of any of the colouring agents listed in paragraph (a) on a substratum of
- (i) alumina,
- (ii) blanc fixe,
- (iii) gloss white,
- (iv) clay,
- (v) zinc oxide,
- (vi) talc,
- (vii) rosin,
- (viii) aluminum benzoate,
- (ix) calcium carbonate, or
- (x) any combination of the substances listed in subparagraphs (i) to (ix).

(4) The following colouring agents are permitted in drugs for external use, namely,

3-10-02

(a) ACID VIOLET 43 (Ext. D & C Violet No. 2; C.I. No. 60730),
ALIZUROL, PURPLE SS (D&C Violet No. 2; C.I. No. 60725),
ANNATTO (C.I. No. 75120),
30-8-95 BISMUTH OXYCHLORIDE (C.I. No. 77163),
CHROMIUM HYDROXIDE GREEN (PIGMENT GREEN 18 (C.I. No. 77289)),
DEEP MAROON (D&C Red No. 34; C.I. No. 15880:1),
DIBROMOFLUORESCEIN (SOLVENT RED 72 (C.I. No. 45370:1); ORANGE No. 5 (D & C Orange No. 5)),
5-4-05 FERRIC FERROCYANIDE (C.I. No. 77510),
30-8-95 GUANINE (C.I. No. 75170),
MANGANESE VIOLET (C.I. No. 77742),
MICA (C.I. No. 77019),

ORANGE II (D&C Orange No. 4; C.I. No. 15510),
29-5-86 PYRANINE CONCENTRATED (D&C Green No. 8; C.I. No. 59040),
QUINIZARIN GREEN SS (D&C Green No. 6; C.I. No. 61565),
TONEY RED (D&C Red No. 17; C.I. No. 26100),
URANINE ACID FORM (D&C Yellow No. 7; C.I. No. 45350:1),
URANINE SODIUM SALT (D&C Yellow No. 8; C.I. No. 45350),
30-8-95 ZINC OXIDE (C.I. No. 77947);

(b) preparations made by extending any of the colouring agents listed in paragraph (a) on a substratum of
(i) alumina,
(ii) blanc fixe,
(iii) gloss white,
(iv) clay,
(v) zinc oxide,
(vi) talc,
(vii) rosin,
(viii) aluminum benzoate,
(ix) calcium carbonate, or
(x) any combination of the substances listed in subparagraphs (i) to (ix); and

(c) preparations made by extending any sodium, potassium, aluminum, barium, calcium, strontium or zirconium salt of any of the colouring agents listed in paragraph (a) on a substratum of
(i) alumina,
(ii) blanc fixe,
29-11-84 (iii) gloss white,
(iv) clay,
(v) zinc oxide,
(vi) talc,
(vii) rosin,
(viii) aluminum benzoate,
(ix) calcium carbonate, or
(x) any combination of the substances listed in subparagraphs (i) to (ix).

(5) Subsections (1) and (2) do not apply in respect of a drug that is represented as being solely for use in the disinfection, for disease prevention, of
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(a) medical devices;
(b) health care facilities; or
(c) premises in which food is manufactured, prepared or kept.

Schedule F Drugs

10-7-80 **C.01.041.** (1) In this section and sections C.01.041.1 to C.01.046, "Schedule F Drug" means a drug listed or described in Schedule F to these Regulations.

(1.1) Subject to sections C.01.043 and C.01.046, no person shall sell a substance containing a Schedule F drug unless

4-8-93 (a) the sale is made pursuant to a verbal or written prescription received by the seller; and
(b) where the prescription has been transferred to the seller under section C.01.041.1, the requirements of section C.01.041.2 have been complied with.

(2) Where the prescription for a Schedule F Drug is written, the person selling the drug shall retain the prescription for at least two years from the date of filling.

(3) Where the prescription for a Schedule F Drug is verbal, the person to whom the prescription is communicated by the practitioner shall forthwith reduce the prescription to writing and the person selling the drug shall retain that written prescription for a period of at least two years from the date of filling.

(4) The person reducing a verbal prescription to writing shall indicate on the written prescription

25-3-65 (a) the date and number of the prescription;
(b) the name and address of the person for whose benefit the prescription is given;
20-4-93 (c) the proper name, common name or brand name of the specified drug and the quantity thereof;
(d) his name and the name of the practitioner who issued the prescription; and
(e) the directions for use given with the prescription, including whether or not the practitioner authorized the refilling of the prescription and, if the prescription is to be refilled, the number of times it may be refilled.

4-5-78 (5) Subsections (1.1) to (4) do not apply to a substance containing

(a) chloral hydrate in preparations for external use, where it constitutes not more than 1% of the substance, or

9-5-72 (b) hexachlorophene and its salts, where it constitutes not more than 0.75% of the substance, calculated as hexachlorophene.

C.01.041.1 A pharmacist may transfer to another pharmacist a prescription for a Schedule F Drug.

4-5-78 **C.01.041.2** A pharmacist to whom a prescription has been transferred under section C.01.041.1 shall not sell a drug pursuant thereto until

(a) he has obtained from the pharmacist transferring the prescription his name and address, the number of authorized refills remaining and the date of the last refill; and

(b) he has

(i) received a copy of the prescription as written by the practitioner or as reduced to writing as required by subsections C.01.041(3) and (4), as the case may be, or

(ii) where the prescription has been transferred to him verbally, reduced the prescription to writing indicating therein the information specified in subsection C.01.041(4).

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C.01.041.3 The pharmacist to whom a prescription for a Schedule F Drug is transferred under section C.01.041.1 shall retain in his files for a period of two years the information and documents referred to in section C.01.041.2.

C.01.041.4 A pharmacist who transfers a prescription under section C.01.041.1

(a) shall enter on the original of the prescription or in a suitable record of prescriptions kept under the name of each patient, the date of transfer; and

(b) shall not make any further sales under the prescription nor transfer it to another pharmacist.

25-3-65 **C.01.042.** (1) No person shall refill a prescription for a Schedule F Drug unless the practitioner so directs and no person shall refill such a prescription more times than the number of times prescribed by the practitioner.

(2) The person filling or refilling a prescription for a Schedule F Drug shall enter on the original of the prescription or in a suitable record of prescriptions kept under the name of each patient

4-5-78 (a) the date of filling;

(b) the date of each refill, if applicable;

(c) the quantity of drug dispensed at the original filling and each refill; and

(d) his name.

C.01.043. (1) A person may sell a Schedule F Drug, without having received a prescription therefor, to

(a) a drug manufacturer;

(b) a practitioner;

(c) a wholesale druggist;

(d) a registered pharmacist;

25-3-65 (e) a hospital certified by the Department of National Health and Welfare;

(f) a Department of the Government of Canada or of a province, upon receipt of a written order signed by the Minister thereof or his duly authorized representative; or

(g) any person, upon receipt of a written order signed by the Director.

(2) Where a person makes a sale authorized by paragraph (f) or (g) of subsection (1), he shall retain the written order for the drug for a period of at least two years from the date of filling the order.

20-4-93 **C.01.044.** (1) Where a person advertises to the general public a Schedule F Drug, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.

(2) Subsection (1) does not apply where

(a) the drug is listed in Part II of Schedule F; and

4-8-93 (b) the drug is

(i) in a form not suitable for human use, or

(ii) labelled in the manner prescribed by paragraph C.01.046(b).

*(R) Minor correction

C.01.045. (1) Subject to subsection (2), no person other than

(a) a practitioner;
(b) a drug manufacturer;
(c) a wholesale druggist;
5-3-65 (d) a registered pharmacist; or
(e) a resident of a foreign country while a visitor in Canada,
shall import a Schedule F Drug.

4-8-93 (2) Any person may import a Schedule F Drug listed in Part II of Schedule F if the drug is imported in such form or so labelled that it could be sold by that person pursuant to section C.01.046.

C.01.046. A person may sell a drug listed or described in Part II of Schedule F to the Regulations, without having received a prescription therefor, if

(a) the drug is in a form not suitable for human use; or
17-5-01 (b) the principal display panel of both the inner label and the outer label carries, in both official languages, the statement "For Veterinary Use Only/Pour usage vétérinaire seulement" or "Veterinary Use Only/Usage vétérinaire seulement", immediately following or preceding the brand name, proper name or common name, in type size not less than one-half as large as the largest type on the label.

C.01.047. Revoked by P.C. 1980-1849 of July 10, 1980

20-4-93 **C.01.048.** (1) Where a person who is a physician, dentist, veterinary surgeon or pharmacist registered and entitled to practise that person's profession in a province has signed an order specifying the brand name, proper name or common name and the quantity of a drug, other than

14-5-97 (a) a narcotic as defined in the *Narcotic Control Regulations*,
(b) a controlled drug as defined in subsection G.01.001(1), or
(c) a new drug in respect of which a notice of compliance has not been issued under section C.08.004,

4-10-73 the person who receives the order may distribute the drug to the physician, dentist, veterinary surgeon or pharmacist as a sample if the drug is labelled in accordance with these Regulations.

(2) An order referred to in subsection (1) may provide that the order be repeated at specified intervals during any period not exceeding six months.

C.01.049. A person who, under section C.01.048, distributes a drug as a sample shall

(a) maintain records showing
(i) the name, address and description of each person to whom the drug is distributed,
20-4-93 (ii) the brand name, quantity and form of the drug distributed, and
(iii) the date upon which each such distribution was made; and

25-7-63 (b) keep those records and all orders received for drugs in accordance with section C.01.048 for a period of not less than two years from the date upon which the distribution referred to in the records was made.

Recalls

21-5-82 **C.01.051.** Where a manufacturer who sells a drug in dosage form or a person who imports into and sells in Canada a drug in dosage form commences a recall of the drug, the manufacturer or importer shall forthwith submit to the Director the following information:

20-4-93 (a) the proper name of the drug, the common name of the drug if there is no proper name, the brand name of the drug and the lot number;
(b) in the case of an imported drug, the names of the manufacturer and importer;
(c) the quantity of the drug manufactured or imported;
21-5-82 (d) the quantity of the drug distributed;
(e) the quantity of the drug remaining on the premises of the manufacturer or importer;
(f) the reasons for initiating the recall; and
(g) a description of any other action taken by the manufacturer or importer with respect to the recall.

C.01.052. Revoked by P.C. 1982-524 of May 21, 1982.

21-5-82 **C.01.055.** Revoked by P.C. 1982-524 of May 21, 1982.

C.01.056. Revoked by P.C. 1982-524 of May 21, 1982.

Limits of Variability

C.01.061. (1) Where the net amount of a drug in a package is not expressed on the label in terms of number of dosage units, any 10 packages of the drug selected as provided by official method DO-31, *Determination of Net Contents*, dated December 7, 1988, shall contain an amount of the drug such that, when determined by that official method, the average of the net amounts of the drug in the 10 packages is not less than the net amount of the drug shown on the label.

(2) Where the net amount of a drug in a package is expressed on the label in terms of the number of dosage units, any 10 packages of the drug selected as provided by official method DO-31, *Determination of Net Contents*, dated December 7, 1988, shall contain a number of units such that, when determined by that official method,

(a) the average number of dosage units in the 10 packages is not less than the number of dosage units shown on the label;
(b) no package contains less than the number of dosage units shown on the label except as provided in the table; and
14-5-97 (c) where the drug is a controlled drug as defined in subsection G.01.001(1) or a narcotic as defined in the *Narcotic Control Regulations*, no package contains more than the number of dosage units shown on the label except as provided in the table to this section.

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TABLE

Item	Column I Labelled Number of Dosage Units Per Package	Column II Permitted Variation from the Labelled Number
1.	50 or less	0
2.	More than 50, but less than 101	1
3.	101 or more	the greater of 1 unit or 0.75% of the labelled number, rounded up to the next whole number

1-11-94 **C.01.062.** (1) Subject to subsections (2) to (5), no manufacturer shall sell a drug in dosage form where the amount of any medicinal ingredient therein, determined using an acceptable method, is

7-11-95 (a) less than 90.0 per cent of the amount of the medicinal ingredient shown on the label; or
(b) more than 110.0 per cent of the amount of the medicinal ingredient shown on the label.

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(2) Subject to subsection (5), where a drug in dosage form contains a medicinal ingredient that is a volatile substance of botanical origin or its synthetic equivalent, the amount of that ingredient, determined using an acceptable method, shall be

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(a) not less than 85.0 per cent of the amount of the medicinal ingredient shown on the label; and

(b) not more than 120.0 per cent of the amount of the medicinal ingredient shown on the label.

(3) Subject to subsection (5), where a drug in capsule form contains a medicinal ingredient that is a vitamin in a fish-liver oil, no variation from the amount of the medicinal ingredient as shown on the label, determined using an acceptable method, is permitted other than that which is in accordance with the variation for that fish-liver oil as stated in any publication whose name is referred to in Schedule B to the Act.

(4) Subject to subsection (5), where a drug in dosage form contains a medicinal ingredient that is a vitamin, no variation from the amount of the medicinal ingredient shown on the label, determined using an acceptable method, is permitted other than the variation set out in column III or IV of an item of the table to this section opposite the vitamin set out in column I of that item for the amount of vitamin set out in column II of that item.

(5) Subsections (1) to (4) do not apply in respect of

(a) a drug for which a notice of compliance has been issued pursuant to section C.08.004;

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(b) Repealed by P.C. 1998-1461 of August 26, 1998.

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(c) a drug for which a standard is contained in any publication whose name is referred to in Schedule B to the Act;

(d) a drug described in Schedule C or D to the Act or Division 6 of Part C of these Regulations; or

(e) a drug for which a drug identification number has been assigned under subsection C.01.014.2(1) and in respect of which

(i) the conditions of pharmaceutical production and quality control are suitable for controlling the identity, quality, purity, stability, safety, strength and potency of the drug,

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(ii) all labels, package inserts, product brochures and file cards to be used in connection with the drug make proper claims in respect of the drug,

(iii) the drug can, without undue foreseeable risk to humans, be used for the purposes and under the conditions of use recommended by the manufacturer, and

(iv) the drug is effective for the purposes and under the conditions of use recommended by the manufacturer.

TABLE

Item	*Column I* *Vitamin*	*Column II* *Recommended daily dose*	*Column III* *Limits of variation when the recommended daily dose shown on label is equal to or less than amount set out in column II*	*Column IV* *Limits of variation when the recommended daily dose shown on label is greater than amount set out in column II*
1.	vitamin A (or as β-carotene)	10 000 I.U.	90.0 - 165.0 %	90.0 - 115.0 %
2.	thiamine	4.5 mg	90.0 - 145.0 %	90.0 - 125.0 %
3.	riboflavin	7.5 mg	90.0 - 125.0 %	90.0 - 125.0 %
4.	niacin or niacinamide	45 mg	90.0 - 125.0 %	90.0 - 125.0 %
5.	pyridoxine	3 mg	90.0 - 125.0 %	90.0 - 125.0 %
6.	**d**-pantothenic acid	15 mg	90.0 - 135.0 %	90.0 - 125.0 %
7.	folic acid	0.4 mg	90.0 - 135.0 %	90.0 - 115.0 %
8.	vitamin B_{12}	14 µg	90.0 - 135.0 %	90.0 - 125.0 %
9.	vitamin C	150 mg	90.0 - 145.0 %	90.0 - 125.0 %
10.	vitamin D	400 I.U.	90.0 - 145.0 %	90.0 - 115.0 %
11.	vitamin E	25 I.U.	90.0 - 125.0 %	90.0 - 125.0 %
12.	vitamin K	0.0 mg		90.0 - 115.0 %
13.	biotin	0.0 mg		90.0 - 135.0 %

7-8-96 **C.01.063.** Revoked by P.C. 1996-1223 of August 7, 1996.

C.01.064. Where a drug is prepared for ophthalmic or parenteral use and contains a preservative ingredient, that ingredient

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(a) shall be present only in an amount necessary to obtain the intended action and that does not pose undue risk to humans or animals; and
(b) shall not interfere with the therapeutic properties of the drug.

7-8-96 **C.01.065.** No person shall sell a drug that is prepared for ophthalmic or parenteral use unless a representative sample of each lot of the drug in its immediate container

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(a) is tested by an acceptable method for identity, and the drug is found to be true to its proper name, or to its common name if there is no proper name;
(b) is tested by an acceptable method for sterility, except
(i) for living vaccines, or
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(ii) where the manufacturer has submitted evidence, satisfactory to the Director to prove that processing controls ensure the sterility of the drug in its immediate container,
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and the drug is found to be sterile; and
(c) is subjected to such further tests satisfactory to the Director to ensure that the drug is safe to use according to directions.

1-12-77 **C.01.066.** No person shall sell a drug in aqueous solution that is prepared for parenteral use unless it has been prepared with non-pyrogenic water produced by distillation or reverse osmosis.

C.01.067. (1) Subject to subsection (2), no person shall sell a drug that is prepared for parenteral use unless a representative sample of each lot of the drug in its immediate container

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(a) is tested by an acceptable method for the presence of pyrogens; and
(b) when so tested, is found to be non-pyrogenic.

(2) Subsection (1) does not apply in respect of a drug that cannot be tested for the presence of pyrogens or that is inherently pyrogenic.

19-11-92 **C.01.068.** Detailed records of the tests required by sections C.01.065 and C.01.067 shall be retained by the manufacturer for a period of at least one year after the expiration date on the label of the drug.

C.01.069. The packaging of a drug that is prepared for parenteral use shall meet the following requirements:

(a) the immediate container shall be of such material and construction that
(i) no deleterious substance is yielded to the drug,
(ii) it is non-reactive with the drug,
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(iii) visual or electronic inspection of the drug is possible,
(iv) protection against environmental factors that cause deterioration or contamination of the drug is provided or, where that protection cannot be provided by the immediate container, it is provided by the secondary packaging, and
(v) a sufficient quantity of the drug is contained to allow withdrawal of the labelled amount of the drug; and
(b) the immediate closures and any material coming into contact with the drug in its immediate container shall meet the requirements of subparagraphs (a)(i) and (ii).

C.01.070. No person shall sell a drug that is a hypodermic tablet that does not completely dissolve in and form a clear solution with water.

Mercuric Chloride Tablets

C.01.071. No person shall sell mercuric chloride tablets for household use that are packaged in lots of two hundred or less, unless

(a) such tablets are
(i) of an irregular or angular shape,
(ii) coloured blue, and
(iii) packed in an immediate container that is readily distinguishable by touch, and

17-5-01 | (b) the principal display panel of both the inner and the outer labels carries in prominent type and in a colour contrasting to that of such labels

(i) the design of a skull and cross-bones, and
(ii) the word "Poison".

C.01.081. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.085. Revoked by P.C. 1980-1850 of July 10, 1980.

Disinfectants

1-12-77 | **C.01.091.** Revoked by P.C. 1977-3383 of December 1, 1977.

Synthetic Sweeteners

4-5-78 | **C.01.101.** (1) Revoked by P.C. 1978-1515 of May 4, 1978.
19-10-78 | (2) Revoked by P.C. 1978-3211 of October 19, 1978.
4-5-78 | (3) Revoked by P.C. 1978-1515 of May 4, 1978.

| **C.01.121.** Revoked by P.C. 1980-1850 of July 10, 1980.

| **C.01.122.** Revoked by P.C. 1980-1850 of July 10, 1980.

Aminopyrine and Dipyrone

| **C.01.131.** No person shall sell Aminopyrine or Dipyrone (a derivative of Aminopyrine) for oral or parenteral use, unless

(a) the inner label carries the statement:
"WARNING: Fatal agranulocytosis may be associated with the use of Aminopyrine and Dipyrone. It is essential that adequate blood studies be made. (See enclosed warnings and precautions)", and
(b) the outer label or the package insert carries the following statements:
4-10-65 | "WARNING: Serious and even fatal agranulocytosis is known to occur after the administration of Aminopyrine or Dipyrone. Fatal agranulocytosis has occurred after short term, intermittent and prolonged therapy with the drugs. Therefore, the use of these drugs should be as brief as possible. Bearing in mind the possibility that such reactions may occur, Aminopyrine or Dipyrone should be used only when other less potentially dangerous agents are ineffective. PRECAUTIONS: It is essential that frequent white blood cell counts and differential counts be made during treatment with these drugs. However, it is emphasized that agranulocytosis may occur suddenly without prior warning. The drug should be discontinued at the first evidence of any alteration of the blood count or sign of agranulocytosis, and the patient should be instructed to discontinue use of the drug at the first indication of sore throat or sign of other infection in the mouth or throat (pain, swelling, tenderness, ulceration)."

4-10-65 **C.01.132.** No person shall disseminate to a practitioner promotional literature about Aminopyrine or Dipyrone unless the statements set out in section C.01.131 are included in such literature.

4-10-65 **C.01.133.** The provision of section C.01.131 and C.01.132 do not apply to preparations containing Aminopyrine or Dipyrone that are

(a) dispensed by a pharmacist pursuant to a prescription; or
(b) sold for veterinary use only.

Coated Potassium Salts

C.01.134. No person shall sell coated tablets containing potassium salts, with or without thiazide diuretics, unless the inner label thereof or the package insert carries the following statement:
31-1-66 "WARNING: A probable association exists between the use of coated tablets containing potassium salts, with or without thiazide diuretics, and the incidence of serious small bowel ulceration. Such preparations should be used only when adequate dietary supplementation is not practical, and should be discontinued if abdominal pain, distention, nausea, vomiting or gastro-intestinal bleeding occur."

4-10-65 **C.01.135.** No person shall disseminate to a practitioner promotional literature about coated tablets containing potassium salts, with or without thiazide diuretics, unless the statement set out in section C.01.134 is included in such literature.

C.01.136. The provisions of section C.01.134 and C.01.135 do not apply to coated tablets containing potassium salts with or without thiazide diuretics that

4-10-65 (a) are sold for veterinary use only;
(b) are dispensed by a pharmacist pursuant to a prescription; or
(c) contain 100 milligrams or less of elemental potassium per tablet.

New Drugs

C.01.301-307. Revoked by P.C. 1963-1493 of 10th October 1963.

See Division 8, Part C.

Antibiotics

C.01.401. Except as provided in these Regulations, an antibiotic for other than parenteral use shall, in addition to meeting the requirements of section C.01.004, carry on both the inner label and outer label the potency of the drug, expressed in terms of International Units where established or, if no International Unit has been established, in terms of units, milligrams, micrograms or fractions of a gram,

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(a) per gram in the case of solids or viscous liquids;
(b) per millilitre in the case of other liquids; and
(c) per individual dosage or dispensing form in the case of antibiotic preparations put up in individual dosage or dispensing form.

19-11-92 **C.01.402.** Revoked by P.C. 1992-2327 of November 19, 1992.

C.01.410. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.411. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.412. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.420. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.421. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.422. Revoked by P.C. 1980-1850 of July 10, 1980.

Chloramphenicol

C.01.430. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.431. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.432. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.433. No person shall sell chloramphenicol and its salts and derivatives, for oral or parenteral use, unless

(a) the inner label carries a warning statement to the effect that
  (i) bone marrow depression has been associated with the use of chloramphenicol, and
  (ii) the enclosed warnings and precautions should be read carefully; and

(b) the outer label or the package insert carries the following:
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  (i) a warning statement to the effect that chloramphenicol should not be used in the treatment or prophylaxis of minor infections or where it is not indicated, as in colds, influenza, or infections of the upper respiratory tract; that some degree of depression of the bone marrow is commonly seen during therapy, is dose-related and is potentially reversible; that blood studies may detect early changes and; that the other type of bone marrow depression, a sudden, delayed and usually fatal bone marrow hypoplasia that may occur without warning, is very rare, and
  (ii) a statement of precautions to be taken to the effect that it is essential that appropriate blood studies be make during treatment with chloramphenicol and that while blood studies may detect early peripheral blood changes, such studies cannot be relied on to detect the rare and generally irreversible bone marrow depression prior to development of aplastic anaemia.

24-7-61 **C.01.434.** The provisions of section C.01.433 do not apply to chloramphenicol and its salts or derivatives sold by a registered pharmacist.

24-7-61 **C.01.435.** No person shall disseminate to a practitioner promotional literature about chloramphenicol and its salts or derivatives for oral or parenteral use unless the statements set out in paragraph (b) of section C.01.433 are included in such literature.

24-7-61 **C.01.436.** The provisions of sections C.01.433 and C.01.435 do not apply to a drug sold solely for veterinary use.

C.01.440. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.441. Revoked by P.C. 1980-1850 of July 10, 1980.

C.01.442. Revoked by P.C. 1980-1850 of July 10, 1980.

*(R) Minor correction

Sections C.01.450, C.01.451, C.01.452, C.01.460, C.01.461, C.01.462, C.01.470, C.01.471, C.01.472, C.01.480, C.01.490, C.01.491, C.01.492, C.01.493, C.01.494, C.01.495, C.01.496, C.01.497, C.01.510, C.01.511, C.01.512, C.01.513, C.01.520, C.01.521, C.01.522, C.01.530, C.01.531, C.01.532, C.01.540, C.01.541, C.01.542, C.01.550, C.01.551, C.01.552, C.01.560, C.01.561, C.01.562, C.01.563, C.01.570, C.01.571, C.01.572, C.01.580, C.01.590, C.01.591, C.01.592 are revoked by P.C. 1980-1850 of July 10, 1980 (Pages 86, 87 and 88).

*(R) Minor correction

10-7-80 **C.01.600.** No person shall sell for veterinary use a drug listed in the Table of Limits of Drug Dosage for Adults, other than a drug in a form not suitable for human use, unless both the inner and outer labels carry the statement "For Veterinary Use Only" or "Veterinary Use Only".

4-8-93 **C.01.601.** Revoked by P.C. 1993-1621 of August 4, 1993.

C.01.602. The provisions of C.01.401 and C.01.402 do not apply to an antibiotic in amounts less than 50 parts per million contained in an animal food.

C.01.603. The provisions of C.01.401 (b) and (c) and C.01.402 do not apply to an antibiotic in amounts greater than 50 parts per million contained in an animal food.

10-7-80 **C.01.604.** Both the inner and outer labels of a veterinary drug represented as containing a vitamin shall carry

(a) a statement of the amount of each vitamin present in the drug, expressed in terms of the proper name only of the vitamin in
  (i) International Units per gram or per millilitre for vitamin A, provitamin A, vitamin D, and vitamin E,
  (ii) milligrams per gram in the case of solids or viscous liquids, or per millilitre in the case of other liquids, for thiamine, riboflavin, niacin, niacinamide, pyridoxine, **d**-pantothenic acid, **d**-panthenol, folic acid, ascorbic acid, and vitamin K,
  (iii) micrograms per gram in the case of solids or viscous liquids, or per millilitre in the case of other liquids, for biotin, and vitamin B_{12},
  (iv) Oral Units for vitamin B_{12} with intrinsic factor concentrate, or
  (v) for vitamin products put up in individual dosage or dispensing form, the specified units per individual dosage or dispensing form,
(b) except for drugs in a form not suitable for human use, the statement "For Veterinary Use Only" or "Veterinary Use Only".

10-7-80 **C.01.605.** An antibiotic for parenteral use that is recommended for veterinary use only shall carry on both the inner and outer labels

(a) the potency of the drug expressed in terms of International Units where established, or, if no International Unit has been established, in terms of units, milligrams or fractions of a gram, per gram in the case of solids or viscous liquids, per millilitre in the case of other liquids, or per individual dosage or dispensing form for antibiotic preparations put up in individual dosage or dispensing form, and

19-11-92 (b) Revoked by P.C. 1992-2327 of November 19, 1992;

(c) the statement "For Veterinary Use Only" or "Veterinary Use Only".

21-7-88 **C.01.606.** No person shall sell an antibiotic preparation for the treatment of animals, other than an antibiotic preparation that is a new drug sold pursuant to section C.08.013, unless,

(a) where the preparation is not to be used for lactating animals providing milk to be consumed as food, the inner and outer labels of the preparation carry a statement to that effect; or

21-7-88 (b) where the preparation may be used for lactating animals providing milk to be consumed as food,

(i) there has been submitted, on request, to the Director, acceptable evidence to show the period of time, not exceeding 96 hours, that must elapse after the last treatment with the preparation in order that the milk from treated lactating animals will contain no residue of antibiotics that would cause injury to human health, and

23-9-93 (ii) the principal display panel of the outer label of the preparation, the inner label and the packaging insert, if any, describing the antibiotic preparation carry the warning " **WARNING: MILK TAKEN FROM TREATED ANIMALS DURING TREATMENT AND WITHIN ... HOURS AFTER THE LATEST TREATMENT MUST NOT BE USED AS FOOD**", where the number of hours to be inserted is determined according to evidence submitted pursuant to subparagraph (i).

7-6-90 **C.01.606.1** No person shall sell a product intended for the prevention or treatment of foot rot of cattle if that product contains Ethylenediamine Dihydroiodide (EDDI).

10-7-80 **C.01.607.** Notwithstanding subparagraph C.01.004(1)(c)(ii), the declaration of a lot number is not required on the label of an animal feeding-stuff containing a drug.

C.01.608. The provisions of section C.01.604 do not apply to medicated feeds registered under the Feeding Stuffs Act.

2-1-58 **C.01.609.** Notwithstanding the provisions of section C.01.401(a), the potency of an antibiotic in amounts greater than 50 parts per million contained in a medicated feed registered under the Feeding Stuffs Act may be declared in grams per ton.

4-3-63 **C.01.610.** No person shall sell any substance having oestrogenic activity for administration to poultry that may be consumed as food.

C.01.610.1 No person shall sell a drug for administration to animals that produce food or that are intended for consumption as food if that drug contains

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(a) chloramphenicol or its salts or derivatives;
(b) a 5-nitrofuran compound;
20-11-97 (c) clenbuterol or its salts or derivatives;
13-8-03 (d) a 5-nitroimidazole compound; or
(e) diethylstilbestrol or other stilbene compounds.

C.01.610.2 No person shall sell an antibiotic preparation containing chloramphenicol, its salts or derivatives, for administration to animals that do not produce food and that are not intended for consumption as food unless

(a) both the inner label and outer label of the preparation carry the words "WARNING: FEDERAL LAW PROHIBITS THE ADMINISTRATION OF THIS PREPARATION TO ANIMALS THAT PRODUCE FOOD OR ANIMALS THAT ARE INTENDED FOR CONSUMPTION AS FOOD/MISE EN GARDE: EN VERTU DES LOIS FÉDÉRALES, IL EST INTERDIT D'ADMINISTRER CETTE PRÉPARATION AUX ANIMAUX QUI PRODUISENT DES ALIMENTS OU AUX ANIMAUX DESTINÉS À ÊTRE CONSOMMÉS COMME ALIMENTS";

19-9-91 (b) where the preparation is for parenteral use, the preparation contains, in the form of chloramphenicol sodium succinate, not more than one gram of chloramphenicol per vial;

(c) where the preparation is for ophthalmic use, the preparation contains not more than one per cent chloramphenicol; and

(d) where the preparation is for oral use, the preparation

(i) is in tablet or capsule form and contains not more than one gram of chloramphenicol per tablet or capsule, or

(ii) is in the form of a chloramphenicol palmitate suspension and contains not more than three grams of chloramphenicol per container.

25-3-65

C.01.611. (1) The Director may, in writing, from time to time require the manufacturer of a drug recommended for administration to animals that may be consumed as food

(a) to file with him in respect of that drug a submission, in form and content satisfactory to the Director, describing in detail tests carried out to determine that no residues of the drug, except residues within the limits prescribed by these Regulations, remain in meat, meat by-products, eggs or milk; and

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(b) to print on the principal display panel of the outer label, the inner label and the packaging insert, if any, that describes the drug, a warning that meat, meat by-products, eggs or milk from animals to which the drug has been administered cannot be sold for consumption as food unless there has elapsed since the administration of the drug a period of time specified by the Director, based on a review of the available data with respect to drug residue.

(2) No manufacturer shall sell a drug in respect of which the Director has required a warning to be printed pursuant to paragraph (b) of subsection (1) unless the manufacturer has complied with that request.

16-8-94

C.01.612. Revoked by P.C. 1994-1369 of August 16, 1994.

Contraceptive Drugs

14-1-70

C.01.625. Contraceptive drugs that are manufactured, sold or represented for use in the prevention of conception and that are not listed in Schedule F may be advertised to the general public.

Interpretation

C.01A.001. (1) The definitions in this subsection apply in this Division and in Divisions 2 to 4.

29-11-04 "**antimicrobial agent**" means a drug that is capable of destroying pathogenic micro-organisms and that is labelled as being for use in the disinfection of environmental surfaces or medical devices, as defined in the *Medical Devices Regulations*, that

(a) are not invasive devices as defined in those Regulations; and

(b) are intended to come into contact with intact skin only. (*agent antimicrobien*)

"**batch certificate**" means a certificate issued by the fabricator of a lot or batch of a drug that is exported within the framework of a mutual recognition agreement and in which the fabricator

(a) identifies the master production document for the drug and certifies that the lot or batch has been fabricated, packaged/labelled and tested in accordance with the procedures described in that document;

(b) provides a detailed description of the drug, including

(i) a statement of all properties and qualities of the drug, including the identity, potency and purity of the drug, and

3-10-02 (ii) a statement of tolerances for the properties and qualities of the drug;

(c) identifies the analytical methods used in testing the lot or batch and provides details of the analytical results obtained;

(d) sets out the addresses of the buildings at which the lot or batch was fabricated, packaged/labelled and tested; and

(e) certifies that the lot or batch was fabricated, packaged/labelled and tested in accordance with the good manufacturing practices of the regulatory authority that has recognized those buildings as meeting its good manufacturing practices standards. (*certificat de lot*)

"**class monograph**" means a document prepared by the Department of Health that

17-12-97 (a) lists the types and strengths of medicinal ingredients that may be contained in drugs of a specified class; and

(b) sets out labelling and other requirements that apply to those drugs. (*monographie de classe*)

"**dilute drug premix**" means a drug for veterinary use that results from mixing a drug premix with a feed as defined in section 2 of the *Feeds Regulations, 1983*, with the lowest approved dosage level of the drug. (*prémélange médicamenteux dilué*)

"**dosage form class**" means a parenteral, tablet, capsule, solution, suspension, aerosol, powder, suppository, medical gas or drug premix, or any other dosage form class designated by the Minister. (*classe de forme posologique*)

"**drug premix**" means a drug for veterinary use to which a drug identification number has been assigned, where the directions on its label specify that it is to be mixed with feed as defined in section 2 of the *Feeds Act*. (*prémélange médicamenteux*)

"**fabricate**" means to prepare and preserve a drug for the purposes of sale. (*manufacturer*)

"**import**" means to import into Canada a drug for the purpose of sale. (*importer*)

3-10-02 "**MRA country**" means a country that is a participant in a mutual recognition agreement with Canada. (*pays participant*)

3-10-02 "**mutual recognition agreement**" means an international agreement that provides for the mutual recognition of compliance certification for good manufacturing practices for drugs. (*accord de reconnaisance mutuelle*)

"**package/label**" means to put a drug in its immediate container or to affix the inner or outer label to the drug. (*emballer-étiqueter*)

"**pharmaceutical**" means a drug other than a drug listed in Schedule C or D to the Act. (*produit pharmaceutique*)

3-10-02 "**recognized building**" means, in respect of the fabrication, packaging/labelling or testing of a drug, a building that a regulatory authority that is designated under subsection C.01A.019(1) in respect of that activity for that drug has recognized as meeting its good manufacturing practices standards in respect of that activity for that drug. (*bâtiment reconnu*)

3-10-02 "**regulatory authority**" means a government agency or other entity in an MRA country that has a legal right to control the use or sale of drugs within that country and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with legal requirements. (*autorité réglementaire*)

3-10-02 "**site**" Repealed by P.C. 2002-1710 of October 3, 2002

"**wholesale**" means to sell any of the following drugs, other than at retail sale, where the seller's name does not appear on the label of the drugs:

3-10-02 (a) a drug listed in Schedule C or D to the Act or in Schedule F to these Regulations or a controlled drug as defined in subsection G.01.001(1); or

(b) a narcotic as defined in the *Narcotic Control Regulations*. (*vendre en gros*)

19-12-96 (2) In this Division and in Division 2, "drug" means a drug in dosage form, or a drug that is a bulk process intermediate that can be used in the preparation of a drug listed in Schedule C to the Act or in Schedule D to the Act that is of biological origin. It does not include a dilute drug premix, a medicated feed as defined in section 2 of the *Feeds Regulations, 1983*, a drug that is used only for the purposes of an experimental study in accordance with a certificate issued under section C.08.015 or a drug listed in Schedule H to the Act.

19-12-96 (3) Where the Minister designates additional dosage form classes, the Minister shall make a list of those classes available on request.

C.01A.002. (1) This Division does not apply to

(a) wholesaling a drug premix;
(b) importing or compounding, pursuant to a prescription, a drug that is not commercially available in Canada by one of the following persons, namely,
  (i) a pharmacist,
  (ii) a practitioner, and
  (iii) a person who compounds a drug under the supervision of a practioner;
7-6-01 (c) any activity with respect to a drug that is used only for the purposes of clinical testing in accordance with subsection C.05.006(1) or section C.08.005;
17-12-97 (d) fabricating, packaging/labelling, testing as required under Division 2, distributing as a distributer referred to in section C.01A.003, wholesaling or importing any of the following drugs for which prescriptions are not required and that are for human use in dosage form and not represented as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states set out in Schedule A to the Act, namely,
  (i) homeopathic drugs,
  (ii) drugs that meet the requirements of a class monograph entitled "Vitamin Supplements", "Mineral Supplements", "Dietary Vitamin Supplements" or "Dietary Mineral Supplements", as the case may be, and
  (iii) drugs that
    (A) contain a plant, mineral or animal substance in respect of which therapeutic activity or disease prevention activity is claimed, including traditional herbal medicines, traditional Chinese medicines, ayurvedic (East Indian) medicines and traditional aboriginal (North American) medicines, and
    (B) the medical use of which is based solely on historical and ethnological evidence from references relating to a medical system other than one based on conventional scientific standards; and
29-11-04 (e) fabricating, packaging/labelling, testing, distributing, and importing of antimicrobial agents.

17-12-97 (2) This Division and Divisions 2 to 4 do not apply to the affixing of a label to a previously labelled container.

C.01A.003. This Division and Divisions 2 to 4 apply to the following distributors:

3-10-02 (a) a distributor of a drug listed in Schedule C or D to the Act or in Schedule F to these Regulations, a controlled drug as defined in subsection G.01.001(1) or a narcotic as defined in the *Narcotic Control Regulations*, who does not hold the drug identification number for the drug or narcotic; and
(b) a distributor of a drug for which that distributor holds the drug identification number.

Prohibition

C.01A.004. (1) Subject to subsection (2), no person shall, except in accordance with an establishment licence,

(a) fabricate, package/label, distribute as set out in section C.01A.003, import or wholesale a drug; or
(b) perform the tests, including examinations, required under Division 2.

19-12-96 (2) A person does not require an establishment licence to perform tests under Division 2 if the person holds an establishment licence as a fabricator, a packager/labeller, a distributor referred to in paragraph C.01A.003(b) or an importer.

3-10-02 (3) No person shall carry on an activity referred to in subsection (1) in respect of a narcotic as defined in the *Narcotic Control Regulations* or a controlled drug as defined in subsection G.01.001(1) unless the person holds a licence for that narcotic or drug under the *Narcotic Control Regulations* or Part G of these Regulations, as the case may be.

Application for Establishment Licence

C.01A.005. Subject to section C.01A.006, a person who wishes to apply for an establishment licence shall submit an application to the Minister, in a form established by the Minister, that contains the following information:

(a) the applicant's name, address and telephone number, and their facsimile number and electronic mail address, if any;
(b) the name and telephone number, and the facsimile number and electronic mail address, if any, of a person to contact in case of an emergency;
(c) each activity set out in Table I to section C.01A.008 for which the licence is requested;
(d) each category of drugs set out in Table II to section C.01A.008 for which the licence is requested;
(e) each dosage form class in respect of which the applicant proposes to carry out a licensed activity, and whether it will be in a sterile dosage form;
19-12-96 (f) whether the applicant proposes to carry out a licensed activity in respect of a drug that is a bulk process intermediate;
(g) the address of each building in Canada in which the applicant proposes to fabricate, package/label, test as required under Division 2 or store drugs, specifying for each building which of those activities and for which category of drugs and, for each category,
  (i) the dosage form classes, and whether any drugs will be in a sterile dosage form, and
  (ii) whether any drugs will be bulk process intermediates;
(h) the address of each building in Canada at which records will be maintained;
(i) whether any building referred to in paragraphs (g) and (h) is a dwelling-house;
(j) the drug identification number, if any, or a name that clearly identifies the drug,
3-10-02 (i) for each narcotic as defined in the *Narcotic Control Regulations* or each controlled drug as defined in subsection G.01.001(1) for which the licence is requested, and
  (ii) for each other drug within a category of drugs for which the licence is requested, unless the licence is to perform tests required under Division 2, distribute as set out in paragraph C.01A.003(a), or wholesale;
(k) if any of the buildings referred to in paragraph (g) have been inspected under the Act or these Regulations, the date of the last inspection;
(l) evidence that the applicant's buildings, equipment and proposed practices and procedures meet the applicable requirements of Divisions 2 to 4;
(m) in the case of an importer of a drug that is fabricated, packaged/labelled or tested in an MRA country at a recognized building,
  (i) the name and address of each fabricator, packager/labeller and tester of the drug and the address of each building at which the drug is fabricated, packaged/labelled or tested, specifying for each building the activities and the category of drug and
    (A) the dosage form class and whether the drug is in a sterile dosage form, and
    (B) whether the drug is a bulk process intermediate,
3-10-02 (ii) in respect of each activity done in an MRA country at a recognized building, the name of the regulatory authority that is designated under subsection C.01A.019(1) in respect of that activity for that drug and that has recognized that building as meeting its good manufacturing practices standards in respect of that activity for that drug, and
  (iii) in respect of any other activities,
    (A) a certificate from a Canadian inspector indicating that the fabricator's, packager/labeller's or tester's buildings, equipment, practices and procedures meet the applicable requirements of Divisions 2 to 4, or
    (B) other evidence establishing that the fabricator's, packager/labeller's or tester's buildings, equipment, practices and procedures meet the applicable reqirements of Divisions 2 to 4;
(n) in the case of any other importer, the name and address of each fabricator, packager/labeller and tester of the drugs proposed to be imported and the address of each building at which the drugs will be fabricated, packaged/labelled and tested, specifying for each building which of those activities and for which category of drugs and, for each category,
  (i) the dosage form classes and whether any drugs will be in a sterile dosage form, and
  (ii) whether any drugs will be bulk process intermediates; and
(o) in the case of an importer referred to in paragraph (n),
  (i) a certificate from a Canadian inspector indicating that the fabricator's, packager/labeller's and tester's buildings, equipment, practices and procedures meet the applicable requirements of Divisions 2 to 4, or
  (ii) other evidence establishing that the fabricator's, packager/labeller's and tester's buildings, equipment, practices and procedures meet the applicable requirements of Divisions 2 to 4.

C.01A.006. (1) A person who wishes to amend an establishment licence shall submit an application to the Minister, in a form established by the Minister, that contains the applicable information specified in section C.01A.005.

(2) An establishment licence must be amended where the licensee proposes

(a) to add an activity or category of drugs, as set out in the tables to section C.01A.008;

(b) in respect of a category of drugs and activity indicated in the licence, to authorize sterile dosage forms of the category;

(c) to add any building in Canada at which drugs are authorized to be fabricated, packaged/labelled, tested as required under Division 2 or stored, or to add, for an existing building, an authorization to fabricate, package/label, test or store a category of drugs, or sterile dosage forms of the category; and

(d) in addition to the matters set out in paragraphs (a) to (c), in the case of an importer,

(i) to add a fabricator, packager/labeller or tester of a drug,

(ii) to amend the name or address of a fabricator, packager/labeller or tester indicated in the licence, and

19-12-96 (iii) if the address of the buildings at which drugs are authorized to be fabricated, packaged/labelled or tested is indicated in the licence, to add additional buildings or, for an existing building, to add an authorization to fabricate, package/label or test a category of drugs, or sterile dosage forms of the category.

C.01A.007. (1) The Minister may, on receipt of an application for an establishment licence or an amended establishment licence, require the submission of further details pertaining to the information contained in the application that are necessary to enable the Minister to process the application.

(2) When considering an application for an establishment licence or an amended establishment licence, the Minister may require that

(a) an inspection be made during normal business hours of any building referred to in paragraph C.01A.005(g) or (h); and

(b) the applicant, if a fabricator, a packager/labeller, a person who performs tests required under Division 2, a distributor referred to in paragraph C.01A.003(b) or an importer, supply samples of any material to be used in the fabrication, packaging/labelling or testing of a drug.

Issuance

C.01A.008. (1) Subject to section C.01A.010, the Minister shall, on receipt of the information and material required by sections C.01A.005 to C.01A.007, issue or amend an establishment licence.

(2) The establishment licence shall indicate

3-10-02 (a) each activity that is authorized and the category of drugs for which each activity is authorized, as set out in the tables to this section, specifying for each activity and category whether sterile dosage forms are authorized;

(b) the address of each building in Canada at which a category of drugs is authorized to be fabricated, packaged/labelled, tested as required under Division 2 or stored, specifying for each building which of those activities and for which category of drugs, and whether sterile dosage forms of the category are authorized; and

(c) in addition to the matters referred to in paragraphs (a) and (b), in the case of an importer,

3-10-02 (i) the name and address of each fabricator, packager/labeller and tester from whom the importer is authorized to obtain the drug for import, and

(ii) the address of each building at which the drug is authorized to be fabricated, packaged/labelled or tested, specifying for each building the activities and the category of drugs that are authorized, and whether sterile dosage forms are authorized.

(3) The Minister may indicate in an establishment licence a period for which records shall be retained under Division 2 that, based on the safety profile of the drug or materials, is sufficient to ensure the health of the consumer.

(4) The Minister may, in addition to the requirements of subsection (2), set out in an establishment licence terms and conditions respecting

(a) the tests to be performed in respect of a drug, and the equipment to be used, to ensure that the drug is not unsafe for use; and
(b) any other matters necessary to prevent injury to the health of consumers, including conditions under which drugs are fabricated, packaged/labelled or tested.

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TABLE I

Item	*Activities*
1.	Fabricate
2.	Package/label
3.	Perform the tests, including any examinations, required under Division 2
4.	Distribute as set out in paragraph C.01A.003(a)
5.	Distribute as set out in paragraph C.01A.003(b)
6.	Import
7.	Wholesale

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TABLE II

Item	*Categories of drugs*
1.	Pharmaceuticals
2.	Vaccines
3.	Whole blood and its components
4.	Drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components
5.	Drugs listed in Schedule C to the Act
6.	Drugs listed in Schedule F to these Regulations, controlled drugs as defined in subsection G.01.001(1) and narcotics as defined in the *Narcotic Control Regulations*

27-6-97 **C.01A.009.** An establishment licence expires on December 31 of each year.

Refusal to Issue

C.01A.010. (1) The Minister may refuse to issue or amend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if

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(a) the applicant has made a false or misleading statement in relation to the application for the licence; or
(b) the applicant has had an establishment licence suspended in respect of the matter.

(2) The Minister shall refuse to issue or amend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if the Minister has reasonable grounds to believe that issuing or amending an establishment licence in respect of the matter would constitute a risk to the health of the consumer.

(3) Where the Minister refuses to issue or amend an establishment licence, the Minister shall

(a) notify the applicant in writing of the reasons for the refusal; and
(b) give the applicant an opportunity to be heard.

Terms and Conditions

23-3-00 **C.01A.011.** (1) Every person who holds an establishment licence shall comply with

19-12-96 (a) the requirements and the terms and conditions of the establishment licence; and
(b) the applicable requirements of Divisions 2 to 4.

23-3-00 (2) Repealed by P.C. 2000-406 of March 23, 2000.

C.01A.012. (1) The Minister may amend the terms and conditions of an establishment licence if the Minister believes on reasonable grounds that an amendment is necessary to prevent injury to the health of the consumer.

(2) The Minister shall give at least 15 days notice in writing to the holder of the establishment licence of the proposed amendment, the reasons for the amendment and its effective date.

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Notification

C.01A.013. Every person who holds an establishment licence shall notify the Minister in writing within 15 days after

(a) there is any change to the information referred to in any of paragraphs C.01A.005(a), (b), (e), (f), (h) and (i), and subparagraphs C.01A.005(g)(i) and (ii); or
(b) an event occurs that results in their being in contravention of any of the applicable requirements of Divisions 2 to 4, where it may affect the quality, safety or efficacy of a drug fabricated, packaged/labelled, tested as required under Division 2 or stored by them.

C.01A.014. (1) No licensee shall carry on a licensed activity in respect of any category of drugs if a change referred to in subsection (2) has occurred in respect of that category, unless

(a) they have filed with the Minister a notice that contains sufficient information to enable the Minister to assess the safety of the drug, taking into account the change; and
19-12-96 (b) the Minister has issued to them a letter indicating that the information will be reviewed and has not, within 90 days after issuing the letter, sent them a notice indicating that the change is not acceptable.

(2) Notification is required in respect of the following changes where they may affect whether a drug can be fabricated, packaged/labelled, tested or stored in accordance with the applicable requirements of Divisions 2 to 4:

(a) changes to the plans and specifications of a building where a drug is fabricated, packaged/labelled, tested or stored;
(b) changes to the equipment that is used in the fabrication, packaging/labelling or testing of a drug;
(c) changes to the practices or procedures; and
3-10-02 (d) in the case of an importer, other than an importer of a drug that is fabricated, packaged/labelled or tested in an MRA country at a recognized building, any change referred to in paragraphs (a) to (c) that relates to the fabricator, packager labeller or tester of the drug being imported.

3-10-02 **C.01A.015.** (1) An importer of a drug that is fabricated, packaged/labelled or tested in an MRA country at a recognized building shall immediately notify the Minister if the fabricator, packager/labeller or tester indicated in the importer's establishment licence no longer holds a valid permit, licence or other authorization issued by the regulatory authority that recognized that building.

(2) The Minister shall, on receiving a notification under subsection (1), amend the importer's establishment licence by removing the name and address of that fabricator, packager/labeller or tester.

Suspension

C.01A.016. (1) Subject to subsection (3), the Minister may suspend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if the Minister has reasonable grounds to believe that

(a) the licensee has contravened any provision of the Act or these Regulations; or
(b) the licensee has made a false or misleading statement in the application for the establishment licence.

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(2) Before suspending an establishment licence, the Minister shall consider

(a) the licensee's history of compliance with the Act and these Regulations; and
(b) the risk that allowing the licence to continue in force would constitute for the health of the consumer.

(3) Subject to subsection C.01A.017(1), the Minister shall not suspend an establishment licence until

(a) an inspector has sent the licensee a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
(b) if corrective action is required, the time set out in the notice has passed without the action having been taken; and
(c) the licensee has been given an opportunity to be heard in respect of the suspension.

C.01A.017. (1) The Minister may suspend an establishment licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health of the consumer, by giving the licensee a notice in writing that states the reason for the suspension.

(2) A licensee may request of the Minister, in writing, that the suspension be reconsidered.

(3) The Minister shall, within 45 days after the date of receiving the request, provide the licensee with the opportunity to be heard.

C.01A.018. The Minister may reinstate an establishment licence after it has been suspended.

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Designation

C.01A.019. (1) For the purposes of this Division and Divisions 2 to 4, a regulatory authority that is set out in column 1 of the table to this section is hereby designated in respect of the activities set out in column 3 for the drug or category of drugs set out in column 2.

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(2) Whole blood and its components are excluded from the drugs and categories of drugs set out in column 2 of the table to this section.

(3) The lot release of drugs listed in Schedule D to the Act is excluded from the activity of testing set out in column 3 of the table to this section.

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TABLE

DESIGNATED REGULATORY AUTHORITIES

Item	Column 1 Regulatory authority	Column 2 Drug or category of drugs	Column 3 Activities
1.	Swissmedic, Swiss Agency for Therapeutic Products, Bern, Switzerland	Pharmaceuticals for human or veterinary use Drugs listed in Schedules C and D to the Act	Fabricating, packaging/labelling, testing
2.	Regional Medicines Inspectorate of Northwestern Switzerland (RFS-NW), Basel, Switzerland	Pharmaceuticals for human or veterinary use Drugs listed in Schedules C and D to the Act	Fabricating, packaging/labelling, testing
3.	Regional Medicines Inspectorate of Eastern and Central Switzerland (RFS-OZ), Zurich, Switzerland	Pharmaceuticals for human or veterinary use Drugs listed in Schedules C and D to the Act	Fabricating, packaging/labelling, testing
4.	Regional Medicines Inspectorate of Southern Switzerland (RFS-S), Ticino, Switzerland	Pharmaceuticals for human or veterinary use Drugs listed in Schedules C and D to the Act	Fabricating, packaging/labelling, testing
5.	Regional Medicines Inspectorate of Western Switzerland (RFS-W), Lausanne, Switzerland	Pharmaceuticals for human or veterinary use Drugs listed in Schedules C and D to the Act	Fabricating, packaging/labelling, testing

Good Manufacturing Practices

19-12-96 **C.02.001.** Revoked by P.C. 1996-1915 of December 19, 1996.

C.02.002. In this Division,

19-12-96 "**drug**" Revoked by P.C. 1996-1915 of December 19, 1996.

"**importer**" Revoked by P.C. 1996-1915 of December 19, 1996.

7-8-85 "**medical gas**" means any gas or mixture of gases manufactured, sold or represented for use as a drug; *(gaz médical)*

"**packaging material**" includes a label; *(matériel d'emballage)*

19-12-96 "**produce**" Revoked by P.C. 1996-1915 of December19, 1996.

"**quality control department**" means a quality control department referred to in section C.02.013; *(service du contrôle de la qualité)*

"**specifications**" means a detailed description of a drug, the raw material used in a drug or the packaging material for a drug and includes

23-3-89 (a) a statement of all properties and qualities of the drug, raw material or packaging material that are relevant to the manufacture, packaging and use of the drug, including the identity, potency and purity of the drug, raw material or packaging material,

(b) a detailed description of the methods used for testing and examining the drug, raw material or packaging material, and

(c) a statement of tolerances for the properties and qualities of the drug, raw material or packaging material. *(spécifications)*

29-11-04 **C.02.002.1** This Division does not apply to fabricating, packaging/labelling, testing, storing and importing of antimicrobial agents.

Sale

23-3-00 **C.02.003.** No distributor referred to in paragraph C.01A.003(b) and no importer shall sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with the requirements of this Division.

Premises

19-12-96 **C.02.004.** The premises in which a lot or batch of a drug is fabricated or packaged/labelled shall be designed, constructed and maintained in a manner that

21-5-82 (a) permits the operations therein to be performed under clean, sanitary and orderly conditions;

(b) permits the effective cleaning of all surfaces therein; and

(c) prevents the contamination of the drug and the addition of extraneous material to the drug.

Equipment

19-12-96 **C.02.005.** The equipment with which a lot or batch of a drug is fabricated, packaged/labelled or tested shall be designed, constructed, maintained, operated and arranged in a manner that

21-5-82 (a) permits the effective cleaning of its surfaces;

(b) prevents the contamination of the drug and the addition of extraneous material to the drug; and

(c) permits it to function in accordance with its intended use.

Personnel

19-12-96 **C.02.006.** Every lot or batch of a drug shall be fabricated, packaged/labelled, tested and stored under the supervision of personnel who, having regard to the duties and responsibilities involved, have had such technical, academic and other training as the Director considers satisfactory in the interests of the health of the consumer or purchaser.

Sanitation

19-12-96 **C.02.007.** (1) Every person who fabricates or packages/labels a drug shall have a written sanitation program that shall be implemented under the supervision of qualified personnel.

(2) The sanitation program referred to in subsection (1) shall include

19-12-96 (a) cleaning procedures for the premises where the drug is fabricated or packaged/labelled and for the equipment used in the fabrication or packaging/labelling; and

(b) instructions on the sanitary fabrication and packaging/labelling of drugs and the handling of materials used in the fabrication and packaging/labelling of drugs.

19-12-96 **C.02.008.** (1) Every person who fabricates or packages/labels a drug shall have, in writing, minimum requirements for the health and the hygienic behaviour and clothing of personnel to ensure the clean and sanitary fabrication and packaging/labelling of the drug.

19-12-96 (2) No person shall have access to any area where a drug is exposed during its fabrication or packaging/labelling if the person

(a) is affected with or is a carrier of a disease in a communicable form, or

21-5-82 (b) has an open lesion on any exposed surface of the body shall have access to any area where a drug during any stage of its production is exposed.

Raw Material Testing

C.02.009. (1) Each lot or batch of raw material shall be tested against the specifications for the raw material prior to its use in the fabrication of a drug.

(2) No lot or batch of raw material shall be used in the fabrication of a drug unless that lot or batch of raw material complies with the specifications for that raw material.

19-12-96 (3) Notwithstanding subsection (1), water may, prior to the completion of its tests under that subsection, be used in the fabrication of a drug.

(4) Where any property of a raw material is subject to change on storage, no lot or batch of that raw material shall be used in the fabrication of a drug after its storage unless the raw material is retested after an appropriate interval and complies with its specifications for that property.

(5) Where the specifications referred to in subsections (1), (2) and (4) are not prescribed, they shall

(a) be in writing;

(b) be acceptable to the Director who shall take into account the specifications contained in any publication mentioned in Schedule B to the Act; and

(c) be approved by the person in charge of the quality control department.

C.02.010. (1) The testing referred to in section C.02.009 shall be performed on a sample taken

(a) after receipt of each lot or batch of raw material on the premises of the fabricator; or

19-12-96 (b) subject to subsection (2), before receipt of each lot or batch of raw material on the premises of the fabricator, if

(i) the fabricator

(A) has evidence satisfactory to the Director to demonstrate that raw materials sold to him by the vendor of that lot or batch of raw material are consistently manufactured in accordance with and consistently comply with the specifications for those raw materials, and

21-5-82 (B) undertakes periodic complete confirmatory testing with a frequency satisfactory to the Director, and

(ii) the raw material has not been transported or stored under conditions that may affect its compliance with the specifications for that raw material.

19-12-96 (2) After a lot or batch of raw material is received on the premises of the fabricator, the lot or batch of raw material shall be tested for identity.

Manufacturing Control

C.02.011. (1) Every fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(b) and importer of a drug shall have written procedures prepared by qualified personnel in respect of the drug to ensure that the drug meets the specifications for that drug.

(2) Every person required to have written procedures referred to in subsection (1) shall ensure that each lot or batch of the drug is fabricated, packaged/labelled and tested in compliance with those procedures.

C.02.012. (1) Every fabricator, packager/labeller, distributor referred to in section C.01A.003, importer and wholesaler of a drug shall maintain

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(a) a system of control that permits complete and rapid recall of any lot or batch of the drug that is on the market; and
(b) a program of self-inspection.

(2) Every fabricator and packager/labeller and, subject to subsections (3) and (4), every distributor referred to in paragraph C.01A.003(b) and importer of a drug shall maintain a system designed to ensure that any lot or batch of the drug fabricated and packaged/labelled on premises other than their own is fabricated and packaged/labelled in accordance with the requirements of this Division.

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(3) The distributor referred to in paragraph C.01A.003(b) of a drug that is fabricated, packaged/labelled and tested in Canada by a person who holds an establishment licence that authorizes those activities is not required to comply with the requirements of subsection (2) in respect of that drug.

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(4) If a drug is fabricated or packaged/labelled in an MRA country at a recognized building, the distributor referred to in paragraph C.01A.003(b) or importer of the drug is not required to comply with the requirements of subsection (2) in respect of that activity for that drug if
(a) the address of the building is set out in that person's establishment licence; and
(b) that person retains a copy of the batch certificate for each lot or batch of the drug received by that person.

Quality Control Department

23-3-00

C.02.013. (1) Every fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(b) and importer shall have on their premises in Canada a quality control department that is supervised by personnel described in section C.02.006.

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(2) The quality control department referred to in subsection (1) shall be a distinct organizational unit that functions and reports to management independently of any other functional unit, including the manufacturing, processing, packaging or sales unit.

C.02.014. (1) No lot or batch of drug shall be made available for sale unless the sale of that lot or batch is approved by the person in charge of the quality control department.

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(2) A drug that is returned to the fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(b) or importer thereof shall not be made available for further sale unless the sale of that drug is approved by the person in charge of the quality control department.

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(3) No lot or batch of raw material or of packaging/labelling material shall be used in the fabrication or packaging/labelling of a drug unless the material is approved for that use by the person in charge of the quality control department.

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(4) No lot or batch of a drug shall be reprocessed without the approval of the person in charge of the quality control department.

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C.02.015. (1) All fabrication, packaging/labelling, testing, storage and transportation methods and procedures that may affect the quality of a drug shall be examined and approved by the person in charge of the quality control department before their implementation.

(2) The person in charge of the control department shall cause to be investigated every complaint on quality that is received and cause corrective action to be taken where necessary.

(3) The person in charge of the quality control department shall cause all tests or examinations required pursuant to this Division to be performed by a competent laboratory.

Packaging Material Testing

C.02.016. (1) Each lot or batch of packaging material shall, prior to its use in the packaging of a drug, be examined or tested against the specifications for that packaging material.

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(2) No lot or batch of packaging material shall be used in the packaging of a drug unless the lot or batch of packaging material complies with the specifications for that packaging material.

(3) The specifications referred to in subsections (1) and (2) shall

(a) be in writing;
(b) be acceptable to the Director who shall take into account the specifications contained in any publication mentioned in Schedule B to the Act; and
(c) be approved by the person in charge of the quality control department.

C.02.017. (1) The examination or testing referred to in section C.02.016 shall be performed on a sample taken

(a) after receipt of each lot or batch of packaging material on the premises of the person who packages a drug; or
(b) subject to subsection (2), before receipt of each lot or batch of packaging material on the premises of the person who packages a drug, if
  (i) that person
    (A) has evidence satisfactory to the Director to demonstrate that packaging materials sold to him by the vendor of that lot or batch of packaging material are consistently manufactured in accordance with and consistently comply with the specifications for those packaging materials, and
    (B) undertakes periodic complete confirmatory examination or testing with a frequency satisfactory to the Director,
  (ii) the packaging material has not been transported or stored under conditions that may affect its compliance with the specifications for that packaging material.

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(2) After a lot or batch of packaging material is received on the premises of the person who packages a drug,

(a) the lot or batch of the packaging material shall be examined or tested for identity; and
(b) the labels shall be examined or tested in order to ensure that they comply with the specifications for those labels.

Finished Product Testing

C.02.018. (1) Each lot or batch of a drug shall, prior to its availability for sale, be tested against the specifications for that drug.

(2) No lot or batch of a drug shall be available for sale unless it complies with the specifications for that drug.

(3) The specifications referred to in subsections (1) and (2) shall

(a) be in writing;
(b) be approved by the person in charge of the quality control department; and
(c) comply with the Act and these Regulations.

23-3-00 **C.02.019.** (1) Subject to subsections (3) and (4), in the case of a packager/labeller, distributor referred to in paragraph C.01A.003(b) or importer, the testing referred to in section C.02.018 shall be performed on a sample taken

19-12-96 (a) after receipt of each lot or batch of the drug on the premises in Canada of the packager/labeller, distributor referred to in paragraph C.01A.003(b) or importer of the drug; or
21-5-82 (b) subject to subsection (2), before receipt of each lot or batch of the drug on the premises described in paragraph (a), if
19-12-96 (i) the packager/labeller, distributor referred to in paragraph C.01A.003(b) or importer
    (A) has evidence satisfactory to the Director to demonstrate that drugs sold to him by the vendor of that lot or batch of the drug are consistently manufactured in accordance with and consistently comply with the specifications for those drugs, and
21-5-82 (B) undertakes periodic complete confirmatory testing with a frequency satisfactory to the Director, and

*(R) Minor correction

(ii) the drug has not been transported or stored under conditions that may affect its compliance with the specifications for that drug.

19-12-96 (2) Where the packager/labeller, distributor referred to in paragraph C.01A.003(b) or importer of a drug received a lot or batch of the drug on their premises in Canada, and the useful life of the drug is more than 30 days, the lot or batch shall be tested for identity, and the packager/labeller shall confirm the identity after the lot or batch is packaged/labelled.

(3) The distributor referred to in paragraph C.01A.003(b) of a drug that is fabricated, packaged/labelled and tested in Canada by a person who holds an establishment licence that authorizes those activities is not required to comply with the requirements of subsections (1) and (2) in respect of that drug.

3-10-02 (4) If a drug is fabricated, packaged/labelled and tested in an MRA country at a recognized building, the distributor referred to in paragraph C.01A.003(b) or importer of that drug is not required to comply with the requirements of subsections (1) and (2) in respect of that drug if

(a) the address of the building is set out in that person's establishment licence; and
(b) that person retains a copy of the batch certificate for each lot or batch of the drug received by that person.

Records

19-12-96 **C.02.020.** (1) Every fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(b) and importer shall maintain on their premises in Canada, for each drug sold,

(a) master production documents for the drug;
19-12-96 (b) evidence that each lot or batch of the drug has been fabricated, packaged/labelled, tested and stored in accordance with the procedures described in the master production documents;
19-12-96 (c) evidence that the conditions under which the drug was fabricated, packaged/labelled, tested and stored are in compliance with the requirements of this Division;
21-5-82 (d) evidence establishing the period of time during which the drug in the container in which it is sold will meet the specifications for that drug; and
(e) adequate evidence of the testing referred to in section C.02.018.

19-12-96 (2) Every distributor referred to in paragraph C.01A.003(b) and importer shall make available to the Director, on request, the results of testing performed on raw materials and packaging/labelling material for each lot or batch of a drug sold.

19-12-96 (3) Every fabricator shall maintain on his premises

(a) the written specifications for the raw material; and
(b) adequate evidence of the testing of the raw materials referred to in section C.02.009.

21-5-82 (4) Every person who packages a drug shall maintain on his premises

(a) the written specifications for the packaging material; and
(b) adequate evidence of the packaging material examination or testing referred to in section C.02.016.

(5) Every fabricator shall maintain on their premises in Canada

(a) detailed plans and specifications of each building in Canada at which they fabricate, package/label or test; and
19-12-96 (b) a description of the design and construction of those buildings.

(6) Every fabricator, packager/labeller and tester shall maintain on their premises in Canada details of the personnel employed to supervise the fabrication, packaging/labelling and testing, including each person's title, responsibilities, qualifications, experience and training.

C.02.021. (1) Subject to subsection (2), all records and evidence on the fabrication, packaging/labelling, testing and storage of a drug that are required to be maintained under this Division shall be retained for a period of at least one year after the expiration date on the label of the drug, unless otherwise specified in the person's establishment licence.

(2) All records and evidence on the testing of raw materials and packaging/labelling materials that are required to be maintained under this Division shall be retained for a period of at least five years after the materials were last used in the fabrication or packaging/labelling of a drug, unless otherwise specified in the person's establishment licence.

C.02.022. Every distributor referred to in section C.01A.003, wholesaler and importer of a drug shall retain records of the sale of each lot or batch of the drug, which enable them to recall the lot or batch from the market, for a period of at least one year after the expiration date of that lot or batch, unless otherwise specified in their establishment licence.

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C.02.023. (1) On receipt of a complaint respecting the quality of a drug, every distributor referred to in paragraph C.01A.003(b) and importer of the drug shall make a record of the complaint and of its investigation and retain the record for a period of at least one year after the expiration date of the lot or batch of that drug, unless otherwise specified in their establishment licence.

(2) On receipt of any information respecting the quality or hazards of a drug, every distributor referred to in paragraph C.01A.003(b) and importer of the drug shall make a record of the information and retain it for a period of at least one year after the expiration date of the lot or batch of that drug, unless otherwise specified in their establishment licence.

19-12-96 **C.02.024.** (1) Every fabricator, packager/labeller, distributor referred to in section C.01A.003, importer and wholesaler shall

21-5-82 (a) maintain records of the results of the self-inspection program required by section C.02.012 and of any action taken in connection with that program; and
(b) retain those records for a period of at least three years.

19-12-96 (2) Every person who fabricates or packages/labels a drug shall

21-5-82 (a) maintain records on the operation of the sanitation program required to be implemented under section C.02.007; and
(b) retain those records for a period of at least three years.

Samples

C.02.025. (1) Every distributor referred to in paragraph C.01A.003(b) and importer of a drug shall retain in Canada a sample of each lot or batch of the packaged/labelled drug for a period of at least one year after the expiration date on the label of the drug, unless otherwise specified in the distributor's or importer's establishment licence.

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(2) The fabricator shall retain a sample of each lot or batch of raw materials used in the fabrication of a drug for a period of at least two years after the materials were last used in the fabrication of the drug, unless otherwise specified in the fabricator's establishment licence.

21-5-82 **C.02.026.** The samples referred to in section C.02.025 shall be in an amount that is sufficient to determine whether the drug or raw material complies with the specifications for that drug or raw material.

Stability

C.02.027. Every distributor referred to in paragraph C.01A.003(b) and importer shall establish the period of time during which each drug in the package in which it is sold will comply with the specifications.

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C.02.028. Every distributor referred to in paragraph C.01A.003(b) and importer shall monitor, by means of a continuing program, the stability of the drug in the package in which it is sold.

Sterile Products

19-12-96 **C.02.029.** In addition to the other requirements of this Division, a drug that is intended to be sterile shall be fabricated and packaged/labelled

(a) in separate and enclosed areas;
21-5-82 (b) under the supervision of personnel trained in microbiology; and
(c) by a method scientifically proven to ensure sterility.

Medical Gases

7-8-85 **C.02.030.** The provisions of sections C.02.025, C.02.027 and C.02.028 do not apply to medical gases.

Schedule C Drugs

C.03.001. In this DIVISION

(a) "**drug**" means a drug listed in Schedule C to the Act that is in dosage form, or a drug that is a bulk process intermediate that can be used in the preparation of a drug listed in Schedule C to the Act that is of biological origin; (*drogue*)

19-12-96 (b) Revoked by P.C. 1996-1915 of December 19, 1996.

(c) Revoked by P.C. 1996-1915 of December 19, 1996.

(d) "**master lot**" means a quantity of a drug from which a lot is prepared for sale by subsequent dilution or mixture,

(e) "**radionuclide generator**" means a radioactive parent and daughter

(i) contained in an ion exchange column, or

18-12-75 (ii) dissolved in a suitable solvent in a liquid-liquid extraction system where the radioactive daughter is separated from its parent by

(iii) elution from the ion exchange column, or

(iv) a solvent extraction procedure.

19-12-96 **C.03.001.1** No distributor referred to in paragraph C.01A.003(b) or importer shall sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with this Division.

C.03.002. Revoked by P.C. 1996-1915 of December 19, 1996.

C.03.003. Revoked by P.C. 1996-1915 of December 19, 1996.

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C.03.004. Revoked by P.C. 1996-1915 of December 19, 1996.

C.03.005. Revoked by P.C. 1996-1915 of December 19, 1996.

8-1-97 | **C.03.006.** to **C.03.011.** are revoked by P.C. 1997-12 of January 8, 1997.

19-12-96 **C.03.012.** On written request from the Director, every fabricator, packager/labeller, tester, distributor referred to in paragraph C.01A.003(b) and importer of a drug shall submit protocols of tests together with samples of any lot or master lot of the drug before it is sold, and no person shall sell a lot of which the protocol or sample fails to meet the requirements of these Regulations.

C.03.013. No person shall fabricate or import a drug that is derived from animal tissue unless the tissue is obtained from a healthy animal free from infectious disease.

C.03.014. (1) Section C.01.004 does not apply to a drug.

(2) Revoked by P.C. 1996-1915 of December 19, 1996.

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(3) Revoked by P.C. 1996-1915 of December 19, 1996.

C.03.015. Every package of a drug listed or described in Schedule F in the Regulations, other than

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(a) a drug sold to a drug fabricator,
(b) a drug dispensed pursuant to a prescription,
(c) a radiopharmaceutical as defined in section C.03.201,
or

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(d) a component or kit as defined in section C.03.205, shall carry the symbol " Pr " on the upper left quarter of the principal display panel of both its inner and outer labels or, in the case of a single dose container, on the upper left quarter of its outer label.

The heading preceding section C.03.030 and sections C.03.030 to C.03.045 are revoked by P.C. 1981-1125 of April 23, 1981.

Sections C.03.050 to C.03.102 (heading "Insulin Preparations") are revoked by P.C. 1982-2379 of August 5, 1982 and renumbered to be C.04.550 to C.04.602 under division 4, heading "Insulin Preparations".

5-8-82 Sections C.03.150 to C.03.156 (heading "Labelling of Insulin Preparations") are revoked by P.C. 1982-2379 of August 5, 1982 and renumbered to be C.04.650 to C.04.656 under division 4, heading "Labelling of Insulin Preparations".

Section C.03.175 to C.03.183 (heading "Anterior Pituitary Extracts" are revoked by P.C. 1982-2379 of August 5, 1982 and renumbered to be C.04.675 to C.04.683 under division 4, heading "Anterior Pituitary Extracts".

Radiopharmaceuticals

19-12-96 **C.03.201.** In these Regulations, "radiopharmaceutical" means a drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons.

1-3-79 **C.03.202.** (1) Every package containing a radiopharmaceutical, other than a radionuclide generator, shall carry,

(a) on both the inner and outer labels,

19-12-96 (i) the proper name of the drug, which proper name, where there is a brand name, shall immediately precede or follow the brand name,

(ii) the name of the distributor referred to in paragraph C.01A.003(b), and

20-4-93 (iii) the lot number; and

(b) on the outer label

19-12-96 (i) the address of the distributor referred to in paragraph C.01A.003(b),

(ii) the standard that the drug professes to meet, if that standard is referred to in any publication mentioned in Schedule B to the Act,

(iii) a statement of the pharmaceutical form or the route of administration of the drug,

(iv) a statement of the recommended use and the recommended radioactivity to be administered for that use, or a reference to an accompanying package insert that shows such information,

19-12-96 (v) the establishment licence number of the distributor preceded by the words "Establishment Licence Number", "Numéro de licence d'établissement" or an abbreviation thereof,

(vi) the radiation warning symbol required by the Atomic Energy Control Regulations and the statement "Caution -- Radioactive Material" "Attention -- produits radioactif",

(vii) the names and a statement of the amounts of any preservatives or stabilizing agents contained in the drug,

(viii) the names and a statement of the amounts of all other non-radioactive contents of the drug,

3-9-74 (ix) a statement of the total radioactivity content of the drug including overfill,

(x) a statement of the total volume of the drug including overfill, except where its contents are entirel in gaseous, capsule or lyophilized form,

(xi) a statement of the concentration of radioactive material in the drug expressed as

(A) units of radioactivity per capsule or

(B) units of radioactivity per unit volume,

except where the contents of the drug are entirely in gaseous or lyophilized form,

(xii) a statement of the specific activity of the drug expressed as units of radioactivity per unit weight of carrier present or the statement "carrier-free" or "sans entraineur", whichever is applicable,

(xiii) a statement of the reference time in respect of the radioactivity values mentioned in subparagraphs (ix), (xi) and (xii), the name of the month being written or designated by letter abbreviation,

(xiv) a statement of the recommended useful life or the date after which the drug is not recommended for use, the name of the month being written or designated by letter abbreviation, and

(xv) a statement of the special storage requirements with reference to temperature and light,

7-6-01 (2) Repealed by P.C. 2001-1042 of June 7, 2001.

(3) Subparagraph (1)(b)(viii) does not apply where the information referred to in that subparagraph is shown on a package insert that accompanies the drug.

1-3-79 (4) Section C.01.005 does not apply to a radiopharmaceutical.

1-3-79 **C.03.203.** (1) Every radionuclide generator shall carry on the inner label

19-12-96 (a) the proper name of the radionuclide generator, which proper name, where there is a brand name, shall immediately precede or follow the brand name;
(b) the name and address of the distributor referred to in paragraph C.01A.003(b);
(c) the lot number;
(d) the standard that the radionuclide generator professes to meet, if that standard is referred to in any publication mentioned in Schedule B to the Act;
19-12-96 (e) the establishment licence number of the distributor preceded by the words "Establishment Licence Number", "Numéro de licence d'établissement" or an abbreviation thereof;
(f) the radiation warning symbol required by the Atomic Energy Control Regulations and the statement "Caution -- Radioactive Material" "Attention -- produits radioactif";
(g) a statement of the total parent radioactivity contained in the radionuclide generator;
(h) a statement of the hour and date at which the radioactivity value mentioned in paragraph (g) is valid, the name of the month being written or designated by letter abbreviation;
(i) a statement of the recommended useful life or the date after which the radionuclide generator is not recommended for use, the name of the month being written or designated by letter abbreviation;
(j) a statement of the recommended useful life of the drug after removal from the radionuclide generator;
(k) a statement of special storage requirements with reference to temperature or shielding;
(l) complete directions for use or a reference to an accompanying package insert that sets out such directions; and
18-12-75 (m) a statement cautioning against the dismantling of the radionuclide generator.

(2) Paragraphs (1)(i) and (j) do not apply where the information referred to in those subparagraph is shown on a package insert that accompanies the radionuclide generator.

C.03.204. (1) No person shall sell a drug containing technetium-99m at any time during the useful life of the drug if the drug also contains a radionuclidic impurity mentioned in the monograph for Sodium Pertechnetate Tc-99m Injection referred to in the publication mentioned in item 7 of Schedule B to the Act, in an amount greater than that shown in the monograph.

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(2) No person shall sell a radionuclide generator from which can be removed a drug that contains technetium-99m, at any time during the useful life of the drug, if the drug also contains a radionuclidic impurity mentioned in the monograph for Sodium Pertechnetate Tc-99m Injection referred to in the publication mentioned in item 7 of Schedule B to the Act, in an amount greater than that shown in the monograph.

Drugs, other than Radionuclides, Sold or Represented for Use in the Preparation of Radiopharmaceuticals

C.03.205. For the purposes of sections C.03.206 to C.03.209,

"component" means
(a) a unit of a drug, other than a radionuclide, separately packaged in a kit for use in the preparation of a radiopharmaceutical, or
(b) an empty vial or other accessory item in a kit;

"kit" means a package
(a) that contains one or more separately packaged units of a drug, other than a radionuclide, and
(b) that may contain empty vials or other accessory items, for use in the preparation of radiopharmaceuticals.

C.03.206. Section C.01.005 and C.04.019 do not apply to a component or kit.

C.03.207. Every component shall be labelled to show

(a) adequate identification of the component and an adequate description of its function;
(b) where applicable, a quantitative list of its ingredients or a reference to the label of the kit that shows such information;
19-12-96 (c) the name of the distributor referred to in paragraph C.01A.003(b);
(d) the lot number;
(e) a statement of any storage requirements with respect to temperature and light;
(f) the date after which the component is not recommended for use, the name of the month being written in full or designated by letter abbreviation; and
1-3-79 (g) adequate directions for use or a reference to the accompanying package insert that shows such directions.

C.03.208. Every kit shall be labelled to show

(a) its proper name;
20-4-93 (b) its brand name, if any;
(c) a list of its contents;
(d) the name and address of the distributor referred to in paragraph C.01A.003(b);
19-12-96 (e) the establishment licence number of the distributor preceded by the words "Establishment Licence Number", "Numéro de licence d'établissement" or an abbreviation thereof;
(f) the lot number;
(g) a statement of any special storage requirements with respect to temperature and light;
(h) the date after which the kit is not recommended for use, the name of the month being written in full or designated by letter abbreviation;
(i) where the label of a component makes reference to the label of the kit that shows information as to the ingredients of the component, a quantitative list of the ingredients of that component;
(j) a statement of the sterility and a pyrogenicity of the components;
(k) adequate directions for preparing the radiopharmaceutical or a reference to the accompanying package insert that shows such directions;
(l) a statement of the duration of the useful life of the prepared radiopharmaceutical;
(m) a statement of the storage requirements for the prepared radiopharmaceutical;
(n) a statement of the recommended use for the prepared radiopharmaceutical and the recommended radioactivity to be administered for that use, or a reference to the accompanying package insert that shows such information; and
(o) a statement of the route of administration of the prepared radiopharmaceutical.
7-6-01 (p) Repealed by P.C. 2001-1042 of June 7, 2001.

C.03.209. A package insert shall be included in every kit and shall show

20-4-93 (a) the proper name and the brand name, if any, of the kit and a description of its use;
(b) a list of the contents of the kit;
19-12-96 (c) the name and address of the distributor referred to in paragraph C.01A.003(b) of the kit;

(d) identification of the radionuclides that can be used to prepare the radiopharmaceutical;
(e) directions for preparing the radiopharmaceutical and a statement of the storage requirements for the prepared radiopharmaceutical;
(f) a statement of the duration of the useful life of the prepared radiopharmaceutical;
(g) a description of the biological actions of the prepared radiopharmaceutical;
1-3-79 (h) indications and contraindications in respect of the prepared radiopharmaceutical;
(i) warnings and precautions in respect of the components and the prepared radiopharmaceutical;
(j) the adverse reactions, if any, associated with the prepared radiopharmaceutical;
(k) where applicable, the pharmacology and toxicology of the prepared radiopharmaceutical or a statement that such information is available on request;
(l) the radiation dosimetry in respect of the prepared radiopharmaceutical;
(m) a statement of the recommended use for the prepared radiopharmaceutical and the recommended radioactivity to be administered for that use;
(n) a statement of the route of administration of the prepared radiopharmaceutical, and
(o) a recommendation that the radiochemical purity and radioactivity content of the prepared radiopharmaceutical be checked prior to administration.

Schedule D Drugs

C.04.001. In this DIVISION

(a) "date of manufacture" means
  (i) in the case of a product for which a standard of potency exists, the date it satisfactorily passes a potency test,
  (ii) in the case of an animal product for which no standard of potency exists, the date of its removal from the animal, and
  (iii) in the case of a product other than an animal product for which no standard of potency exists, the date of cessation of growth,

19-12-96 (b) "drug" means a drug listed in Schedule D to the Act that is in dosage form, or a drug that is a bulk process intermediate that can be used in the preparation of a drug listed in Schedule D to the Act (drogue).

19-12-96 (c) Revoked by P.C. 1996-1915 of December 19, 1996.

(d) Revoked by P.C. 1996-1915 of December 19, 1996.

C.04.001.1 No distributor referred to in paragraph C.01A.003(b) or importer shall sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with this Division.

C.04.002. This Division does not apply to a drug in oral dosage form that contains micro-organisms if the drug is recommended solely for restoring, normalizing or stabilizing the intestinal flora.

C.04.003. The date of issue of a drug shall be the date on which the finished product is removed for cold storage but in any case shall be, not later than

(a) 6 months after the date of manufacture for a drug that has been kept constantly at a temperature not exceeding 10°C.,
(b) 12 months after the date of manufacture for a drug that has been kept constantly at a temperature not exceeding 5°C., or
(c) two years after the date of manufacture for a drug that has been kept constantly at a temperature not exceeding 0°C.

19-12-96 **C.04.004.** Revoked by P.C. 1996-1915 of December 19, 1996.

C.04.005. Revoked by P.C. 1996-1915 of December 19, 1996.

19-12-96 | **C.04.006.** Revoked by P.C. 1996-1915 of December 19, 1996.

8-1-97 | **C.04.007.** to **C.04.012.** are revoked by P.C. 1997-12 of January 8, 1997.

19-12-96 **C.04.013.** Every fabricator and packager/labeller shall safely segregate all work with spore-bearing, pathogenic microorganisms and other infectious agents known to require special precautions in manipulation and shall take such care of equipment and arrangements for supervision that the possibility of contamination of other drugs is avoided.

C.04.014. No person shall conduct laboratory procedures of a diagnostic nature in their premises unless those procedures are entirely segregated from the fabrication, packaging/labelling and testing of drugs.

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C.04.015. On written request from the Director, every fabricator, packager/labeller, tester, distributor referred to in paragraph C.01A.003(b) and importer of a drug shall submit protocols of tests together with samples of any lot of the drug before it is sold, and no person shall sell any lot of that drug if the protocol or sample fails to meet the requirements of these Regulations.

19-12-96 **C.04.016.** All animals from which drugs are prepared and preserved shall be

(a) under the direct supervision of competent medical or veterinary personnel,

19-12-96 (b) kept in quarantine by the fabricator for at least seven days before use; and

(c) healthy and free from infectious disease.

C.04.017. A fabricator shall keep necropsy records of all animals that die or are killed after having been used in the production of a drug.

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C.04.018. A fabricator shall immediately segregate, and report the fact to the Minister, any animal with actual or suspected vesicular stomatitis, foot and mouth disease, encephalomyelitis, infectious anaemia, glanders, anthrax, tetanus or any other serious infectious disease.

C.04.019. The provisions of C.01.004 do not apply to a drug as defined in this DIVISION but every package of such drug shall carry

(a) on both the inner and outer labels

19-12-96 (i) the proper name of the drug, which proper name, where there is a brand name, shall immediately precede or follow the brand name in type not less than one-half the size of that of the brand name,

(ii) the name of the distributor referred to in paragraph C.01A.003(b),

(iii) the potency of the drug, where applicable,

(iv) the recommended dose of the drug,

(v) the lot number,

(vi) the expiration date except upon the inner label of a single-dose container, and

(vii) adequate directions for use, and

(b) on the outer label

(i) the address of the distributor referred to in paragraph C.01A.003(b),

19-12-96 (ii) for whole blood and its components, the establishment licence number of the distributor referred to in paragraph C.01A.003(b), preceded by the words "Establishment Licence Number", "Numéro de licence d'établissement" or an abbreviation thereof,

20-4-93 (iii) the proper name, or the common name if there is no proper name, and the amount, of any preservative in the drug,

19-12-96 (iv) a statement that the drug shall be stored at a temperature of not less than 2°C and not more than 10°C, unless the Minister has received evidence demonstrating that such a statement is not required, and

(v) a statement of the net contents in terms of weight, measure, or number.

17-5-01 **C.04.020.** Except in the case of the following drugs, every package of a drug listed in Schedule F of these Regulations shall carry the symbol " Pr " on the upper left quarter of the principal display panel of both its inner and outer labels or, in the case of a single dose container, on the upper left quarter of its outer label:

19-12-96 (a) a drug sold to a person who holds an establishment licence; and

(b) a drug dispensed pursuant to a prescription.

Bacterial Vaccines, Products Anologous to Bacterial Vaccines

C.04.050. Except as provided in this Division, a bacterial vaccine shall be a sterile suspension of killed cultures of bacteria, with or without the addition of other medication, and shall not include an autogenous vaccine.

C.04.051. No person shall sell a bacterial vaccine unless the culture that has been used in its preparation has been tested by an acceptable method for identity and purity and when so tested it shall be true to name and a pure strain, and a record of the culture shall be maintained which shall include a statement of its origin, properties and characteristics.

C.04.052. No fabricator shall use a substrate (culture medium), in the production of a bacterial vaccine, that contains any horse meat or horse serum.

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C.04.053. A fabricator of bacterial vaccine prepared from a bacterium that does not grow readily in ordinary culture media shall test its sterility in media which are specially favourable to the growth of such bacterium, and it shall be sterile.

18-9-58 **C.04.054.** Except as provided in C.04.083, C.04.084 and C.04.090, both the inner and outer labels of every multiple-dose container and the outer label of every single-dose container of a bacterial vaccine shall carry a statement of

(a) the number of bacteria per millilitre, or the weight of dried substance of bacteria per millilitre,

(b) the number of bacteria per millilitre, or the weight of dried substance of bacteria per millilitre, of each species or immunogenic type for a vaccine that contains a number of different species or immunogenic types of bacteria,

(c) the exact nature and amount of any substance, other than a simple diluent, combined with such vaccine and

(d) the recommended dose,

and the inner label of a single-dose container shall carry a statement that it contains only one dose.

C.04.055. The expiration date of a bacterial vaccine shall be not later than 18 months after the date of manufacture or the date of issue.

Typhoid Vaccine

C.04.060. Cultures of Salmonella typhosa used in the preparation of typhoid vaccine shall be smooth, motile and in the Vi form, with the following antigenic structure IX, XII, Vi;d.-.

C.04.061. No person shall sell any lot of typhoid vaccine unless such lot has been shown to meet a test for potency made by an acceptable method.

Pertussis Vaccine

19-12-96 **C.04.065.** A fabricator shall, in the preparation of pertussis (whooping cough) vaccine, use only strains of Bordetella pertussis that meet the requirements of an antigenic test made by an acceptable method.

18-9-58 **C.04.066.** No person shall sell any lot of pertussis (whooping cough) vaccine unless such lot has been shown to meet a test for potency made by an acceptable method.

18-9-58 **C.04.070.** B.C.G. vaccine shall be prepared from living B.C.G. organisms that

(a) have been obtained directly from a source approved by the Director,
(b) are proved to be non-pathogenic by an acceptable method, and
(c) have a history of successful use in the production of B.C.G. vaccine.

19-12-96 **C.04.071.** No fabricator shall employ any person in the manufacture of B.C.G. vaccine unless such person

(a) has been and remains free from all forms of tuberculous infection,
(b) undergoes every 6 months a medical examination, that shall include an X-ray examination of the chest, for the presence of tuberculosis, such examination being made by a qualified, practising physician who shall sign a certificate of such person's freedom from tuberculosis, and such certificate shall be kept on file and be available at all times, and
(c) resides in a household that is at all times free from active tuberculosis,

nor shall a manufacturer employ such person in any other laboratory position.

19-12-96 **C.04.072.** The preparation, preservation and packaging/labelling of B.C.G. vaccine shall be conducted unde the direct supervision of an experienced bacteriologist who has

(a) not less than three years postgraduate training in bacteriology and immunology,
(b) specialized in the field of bacteriology, and
(c) at least one year of practical experience in the manufacture of B.C.G. vaccine.

19-12-96 **C.04.073.** No fabricator shall permit any culture that is not a B.C.G. culture to be at any time on any premises that are used for the manufacture of B.C.G. vaccine.

19-12-96 **C.04.074.** A packager/labeller shall test by an acceptable method, after filling of the final container, each lot of B.C.G. vaccine for the presence of contaminating micro-organisms and when so tested it shall be free there-from.

C.04.075. Notwithstanding C.04.074 a fluid B.C.G. vaccine may be released for sale if no growth has appeared upon the test culture medium after an incubation of 24 hours, but if there is evidence of the presence of contaminating micro-organisms in any lot during the test period of 10 days the packager/labeller shall at once recall such lot.

19-12-96 **C.04.076.** Every fabricator and packager/labeller shall determine the number of viable B.C.G. organisms in each lot of vaccine by an acceptable method and shall keep a record of the number.

19-12-96 **C.04.077.** A fabricator of B.C.G. vaccine shall keep, at a temperature not exceeding 5.0°C, and for not less than 6 months,

(a) the culture on glycerine-water potato medium from which the Sauton I and Sauton II subcultures were made, and
(b) not less than six vials of the final product

from each lot thereof.

19-12-96 **C.04.078.** Every fabricator and packager/labeller of B.C.G. vaccine shall keep, in form satisfactory to the Minister, continuous clinical records of the use of B.C.G. vaccine in humans.

19-12-96 **C.04.079.** A fabricator of B.C.G. vaccine shall examine pathologically all test animals used and shall immediately report to the Minister any evidence of active, progressive tuberculosis in any such animals.

C.04.080. The expiration date for B.C.G. vaccine shall be not more than

(a) ten days after harvesting in the case of fluid vaccine,
11-7-63 (b) twelve months after harvesting in the case of freeze dried vaccine stored at a temperature of 4°C or above, or
(c) twenty months after harvesting in the case of freeze dried vaccine stored at a temperature below 4°C.

*(R) Minor correction

453, December 17, 1999 (R)
Replaces page 98, December 19, 1996

C.04.081. No person shall sell fluid B.C.G. vaccine that is not packaged in containers sealed by fusion.

18-9-58 **C.04.082.** No inner label shall be required for fluid B.C.G. vaccine in single-dose containers.

C.04.083. The label of fluid B.C.G. vaccine shall carry, in lieu of the statements provided in C.04.054 (a) and (b), a statement of

18-9-58 (a) the weight of bacteria per millilitre, and
(b) the route of administration of the vaccine.

C.04.084. The label of freeze-dried B.C.G. vaccine shall carry, in lieu of the statements provided in C.04.054 (a) and (b), a statement of

18-9-58 (a) the amount of bacteria per vial or per dose, and
(b) the route of administration of the vaccine.

18-9-58 **C.04.085.** The provisions of C.04.019 (b)(iv) do not apply to freeze-dried B.C.G. vaccine.

Products Analogous to Bacterial Vaccines

C.04.090. A product analogous to a bacterial vaccine shall be
(a) a bacterial antigen, other than a bacterial vaccine, such as a lysate, or
(b) an extract prepared from a bacterial culture,
and shall conform to the requirements of these regulations for bacterial vaccines except those of paragraphs (a) and (b) of C.04.054.

C.04.091. The expiration date of a product analogous to a bacterial vaccine shall be not later than 18 months after the date of manufacture or the date of issue, but for dried tuberculin and tuberculin containing at least 50 per cent glycerin the expiration date shall be not later than five years after the date of manufacture or the date of issue, and for all other tuberculins not more than 12 months after the date of manufacture or the date of issue.

Virus and Rickettsial Vaccines

C.04.100. A virus vaccine, rickettsial vaccine, shall be a suspension of, or prepared from, living or killed viruses or rickettsiae.

19-12-96 **C.04.101.** No person shall sell a virus or a rickettsial vaccine unless the fabricator has submitted to the Minister details of the source of the strains of viruses or rickettsiae used, the method of their propagation, the method of fabrication of the vaccine, the methods employed for determining sterility, safety, identity and potency and any other tests required by these Regulations.

19-12-96 **C.04.102.** Upon written request from the Director every fabricator and packager/labeller shall submit with respect to each lot of virus or rickettsial vaccine, when ready for sale, detailed protocols of sterility, safety, identity, potency, and of any other tests required by these regulations.

Smallpox Vaccine

C.04.110. Smallpox vaccine
(a) shall be a virus vaccine;
20-12-05 (b) shall be the living virus of vaccinia or its derivatives obtained from
(i) the vesicles produced in the skin of healthy calves by inoculation of vaccinia virus,
(ii) specifically infected membranes of chick embryos, or
(iii) suitable tissue culture infected with vaccinia virus or its derivatives; and
(c) shall be in fluid or dried form.

19-12-96 **C.04.111.** Every fabricator and packager/labeller shall fabricate and package/label smallpox vaccine only in an independent unit that is isolated from all other laboratory activities, and in or about which no extraneous materials are permitted or stored.

19-12-96 **C.04.112.** A fabricator shall exclude the personnel who care for the vaccine animals from horse stables and paddocks and from contact with horses while smallpox vaccine is being propagated.

C.04.113. Every fabricator and packager/labeller shall dispense smallpox vaccine only in sterile glass containers that are sealed under aseptic conditions.

19-12-96

C.04.114. Every fabricator and packager/labeller shall test smallpox vaccine to establish that it is free from

29-12-66
(a) spore-forming anaerobic micro-organisms;
(b) coagulase positive staphylococci;
(c) haemolytic streptococci; and
(d) any other contaminating pathogenic micro-organisms.

C.04.115. Smallpox vaccine, when tested by acceptable methods,

29-12-66
(a) shall be free from extraneous micro-organisms, in the case of vaccine prepared for use by jet gun; and
(b) shall contain not more than 500 viable non-pathogenic bacteria per millilitre, in the case of vaccine prepared for use by the multiple pressure technique or by scarification.

20-12-05 **C.04.116.** Smallpox vaccine must demonstrate evidence of disease prevention that is at least equivalent to that of a vaccine that

(a) is known to prevent human to human transmission of smallpox; and
(b) meets the potency of equal to or greater than 10^8 pock-forming units per millilitre, as determined using chick embryo chorioallantoic membranes.

19-12-96 **C.04.117.** No person shall sell smallpox vaccine unless

(a) in the case of fluid vaccine, it has been stored at a temperature below -10°C;
29-12-66
(b) in the case of dried vaccine, it has been stored at a temperature below 10°C; and
(c) the outer label carries a statement that it shall be stored at a temperature of not more than 5°C.

C.04.118. Notwithstanding the provisions of section C.04.003 the date of issue of smallpox vaccine shall be not later than

23-11-67
(a) in the case of fluid vaccine, 9 months after the date of manufacture; and
(b) in the case of dried vaccine, 24 months after the date of manufacture.

C.04.119. The expiration date of smallpox vaccine shall not exceed the following, unless supported by evidence of stability satisfactory to the Minister:

20-12-05
(a) in the case of fluid vaccine, 3 months after the date of issue; or
(b) in the case of dried vaccine, 12 months after the date of issue.

29-12-66 **C.04.120.** No inner label shall be required for smallpox vaccine in single-dose containers or when dispensed in capillary tubes.

29-12-66 **C.04.121.** No person shall sell smallpox vaccine to which an antibiotic has been added.

Poliomyelitis Vaccine

18-9-58 **C.04.122.** Poliomyelitis vaccine shall be an aqueous suspension of killed poliomyelitis viruses, Types I, II and III.

18-9-58 **C.04.123.** Poliomyelitis vaccine shall be prepared in acceptable tissue culture medium from strains of poliomyelitis virus proven capable of producing vaccine of acceptable potency.

18-9-58 **C.04.124.** Poliomyelitis vaccine in its final form shall contain not more than 0.35 milligram per millilitre of total nitrogen, nor more than 1 part per million of animal serum.

18-9-58 **C.04.125.** No person shall sell poliomyelitis vaccine unless it has been tested by an acceptable method for potency and safety and when so tested it shall be safe and of acceptable potency.

18-9-58 **C.04.126.** The outer label shall carry a statement of any antibiotic present in the vaccine.

24-7-85 **C.04.127.** The expiration date of the poliomyelitis vaccine shall be not later than 12 months after the date of the last satisfactory potency test unless evidence, satisfactory to the Director, is presented that a longer period is appropriate.

Poliovirus Vaccine, Live, Oral

C.04.128. **Poliovirus Vaccine, Live, Oral** or **Poliovirus Vaccine, Live, Oral (Naming the strains)** shall be prepared from living poliomyelitis virus types I, II and III that

11-7-63
(a) have been obtained directly from a source acceptable to the Director,
(b) are shown to be genetically stable by an acceptable method,
(c) are shown to be non-pathogenic when given orally to humans,
(d) are proved to be capable of multiplying in the human alimentary tract and of producing type specific neutralizing antibodies when administered orally, and
(e) have a history of successful use in the production of polio virus vaccine, live, oral.

19-12-96 **C.04.129.** Poliovirus vaccine, live, oral, shall be fabricated, packaged/labelled and tested in premises separated from buildings where other products are fabricated, packaged.labelled or tested, and from buildings where control tests involving the use of cell lines or virus strains not employed in the fabrication, packaging/labelling and testing of poliovirus vaccine, live, oral, are carried out.

19-12-96 **C.04.130.** No fabricator shall permit the introduction of any bacterial or viral cultures other than those used in the manufacture of poliovirus vaccine, live, oral on any premises that are used for the manufacture of poliovirus vaccine, live, oral.

19-12-96 **C.04.131.** Notwithstanding sections C.04.129 and C.04.130, a fabricator may manufacture other drugs in an area in which poliovirus vaccine, live, oral is manufactured at times when that vaccine is not being manufactured, if

11-7-63
(a) both prior to and following each manufacture the area is cleaned and disinfected by methods acceptable to the Director, and
(b) the manufacturer has received written permission from the Director to carry out such manufacture.

C.04.132. Poliovirus vaccine, live, oral shall be prepared only

11-7-63
(a) in a tissue culture,
(b) in a medium, and
(c) by methods

acceptable to the Director.

19-12-96 **C.04.133.** No fabricator shall sell poliovirus vaccine, live, oral, unless he has tested each lot for extraneous micro-organisms and the vaccine is free therefrom.

19-12-96 **C.04.134.** A fabricator of poliovirus vaccine, live, oral shall test, by a method acceptable to the Director, each lot of vaccine for neurovirulence and for genetic markers and it shall meet the requirements established by the Director.

19-12-96 **C.04.135.** No fabricator shall employ any person in the manufacture of poliovirus vaccine, live, oral unless such person

11-7-63
(a) is free from infectious disease,
(b) has been vaccinated successfully against poliomyelitis by poliovirus vaccine, live, oral, and
(c) has been proved by periodic tests to be a non-carrier of poliomyelitis virus.

19-12-96 **C.04.136.** A fabricator of poliovirus vaccine, live, oral shall not permit the entry to a building in which the vaccine is manufactured of any person who

11-7-63
(a) is not directly concerned with the manufacturing processes, or
(b) has been working on the same day with experimental animals or with infectious agents.

Bacteriophage

11-7-63 **C.04.137.** Bacteriophage shall be a virus preparation with specific lytic action against microorganisms actually or potentially pathogenic.

11-7-63 **C.04.138.** The expiration date of bacteriophage shall be not later than 12 months after the date of manufacture or the date of issue.

Toxins, Toxoids

Schick Test Reagents

C.04.140. Schick test reagents for the diagnosis of susceptibility to diphtheria shall be

(a) diphtheria toxin for Schick test,
(b) Schick control, and
(c) diphtheria toxin for Schick test with control.

C.04.141. Diphtheria toxin for Schick test shall be sterile diluted diphtheria toxin stabilized by an acceptable method.

C.04.142. Schick control shall be suitably diluted

(a) diphtheria toxoid, or
(b) sterile diphtheria toxin heated at a temperature of 95°C for 5 minutes.

C.04.143. The human test dose of diphtheria toxin for Schick test, when aged toxin containing a preservativ is used, shall be determined by

(a) intracutaneous injection into normal guinea pigs in mixture with different proportions of diphtheria antitoxin, and one test dose mixed with 1/750 or more of a unit of antitoxin must cause no local reactio but mixed with 1/1250 or less of a unit of antitoxin must cause a definite local reaction of the type known as the "positive Schick reaction", and
(b) intracutaneous injection into normal guinea pigs without admixture with antitoxin, and 1/50 of one test dose must not cause, and 1/25 of one test dose must cause, a definite local reaction of the type known as the "positive Schick reaction".

*(R) Minor correction

C.04.144. The human test dose of diphtheria toxin for Schick test, when fresh toxin containing no preservative is used, shall be determined by

(a) intracutaneous injection into normal guinea pigs in mixtures with different proportions of diphtheria antitoxin, and one test dose mixed with 1/750 or more of a unit of antitoxin must cause no local reaction, but mixed with 1/1500 or less of a unit of antitoxin must cause a definite local reaction of the type known as the "positive Schick reaction", and

(b) intracutaneous injection into normal guinea pigs without admixture with antitoxin, and 1/100 of one test dose must not cause, and 1/50 of one test dose must cause, a definite local reaction of the type known as the "positive Schick reaction".

C.04.145. The human test dose for the Schick control shall give a negative Schick reaction when injected intracutaneously into normal guinea pigs.

C.04.146. No person shall sell diphtheria toxin for Schick test unless both the inner and the outer labels carry a statement of the number of human test doses it contains together with the name of any stabilizer.

C.04.147. The expiration date of Schick test reagents for the diagnosis of susceptibility to diphtheria shall be not later than 12 months after the date of manufacture or the date of issue.

Diphtheria Toxoid

C.04.160. Liquid diphtheria toxoid shall be sterile, formalized, detoxified diphtheria toxin and shall not contain more than 0.02 per cent free formaldehyde.

C.04.161. Diphtheria toxoid alum precipitated shall be prepared from diphtheria toxoid, and shall not contain more than 15 milligrams of alum per human dose.

C.04.162. The alum used in the preparation of diphtheria toxoid alum precipitated shall contain not less than 99.5 per cent pure potassium alum, A1 K(SO4)2, 12H2O.

19-12-96 | **C.04.163.** No fabricator shall use a culture medium for the production of diphtheria toxin that contains horse protein or Witte peptone or that has not been freed as far as possible from any other allergenic ingredient.

C.04.164. Diphtheria toxin from which diphtheria toxoid is prepared shall have a toxicity, as indicated by an L+ dose, of not more than 0.20 millilitre or by an M.L.D. of not more than 0.0025 millilitre.

19-12-96 | **C.04.165.** A fabricator shall test each bulk container of diphtheria toxoid, before being dispensed into the final containers, for toxicity by an acceptable method, and it shall be non-toxic.

C.04.166. No person shall sell any lot of diphtheria toxoid unless such lot has been shown to meet a test for antigenicity made by an acceptable method.

19-12-96 | **C.04.167.** A fabricator shall fill diphtheria toxoid aseptically into clear glass containers and where preservative is not added shall seal the containers by fusion.

C.04.168. No person shall sell diphtheria toxoid that contains phenol.

C.04.169. No person shall sell diphtheria toxoid unless both the inner and outer labels carry a statement of the appropriate dose for purposes of immunization.

C.04.170. The expiration date of diphtheria toxoid shall be not later than two years after the date of manufacture or the date of issue.

Tetanus Toxoid

C.04.180. Liquid tetanus toxoid shall be sterile, formalized, detoxified tetanus toxin, and shall not contain more than 0.02 per cent free formaldehyde.

C.04.181. Tetanus toxoid alum precipitated shall be prepared from tetanus toxoid, and shall not contain more than 15 milligrams of alum per human dose.

C.04.182. The alum used in the preparation of tetanus toxoid alum precipitated shall contain not less than 99.5 per cent pure potassium alum, Al K(SO4)2, 12H2O.

19-12-96 | **C.04.183.** No fabricator shall use a culture medium for the production of tetanus toxin that contains horse protein or Witte peptone or that has not been freed as far as possible from any other allergenic ingredient.

C.04.184. Tetanus toxin from which tetanus toxoid is prepared shall have a toxicity as indicated by an M.L.D. for the guinea pig of not more than 0.0001 millilitre.

19-12-96 | **C.04.185.** A packager/labeller shall test each bulk container of tetanus toxoid, before being dispensed into the final containers, for toxicity by an acceptable method, and it shall be non-toxic.

C.04.186. No person shall sell any lot of tetanus toxoid unless such lot has been shown to meet a test for antigenicity made by an acceptable method.

C.04.187. No person shall sell tetanus toxoid unless both the inner and outer labels carry a statement of appropriate dose for purposes of immunization.

19-12-96 | **C.04.188.** A fabricator shall fill tetanus toxoid aseptically into clear glass containers and where a preservativ is not added shall seal the container by fusion.

C.04.189. No person shall sell tetanus toxoid that contains phenol.

C.04.190. The expiration date of tetanus toxoid shall be not later than two years after the date of manufacture or the date of issue.

Antitoxins, Antisera

C.04.210. An antitoxin or antiserum shall be the serum or fraction thereof separated from the blood of animals that have been artificially immunized against the by-products or antigenic fractions of specific cultures of micro-organisms, or against specific venoms.

C.04.211. The potency of an antitoxin or antiserum shall be determined by an acceptable method and where applicable the unit of potency shall be the International Unit.

C.04.212. Liquid diphtheria antitoxin shall have a potency of not less than 500 International Units per millilitre.

C.04.213. Liquid tetanus antitoxin shall have a potency of not less than 400 International Units per millilitre.

C.04.214. A liquid antitoxin or antiserum shall contain not more than 20 per cent solids.

C.04.215. A dried antitoxin shall be prepared from a liquid antitoxin and, when reconstituted to the original volume of the liquid antitoxin, shall have a potency not less than that prescribed for such liquid antitoxin.

C.04.216. A dried antitoxin or antiserum shall not contain more than 1 per cent moisture as determined by an acceptable method.

C.04.217. Each lot of antitoxin or antiserum shall be tested by an acceptable method for pyrogenicity and it shall be pyrogen-free, and, after filling into the final containers for identity, and it shall be true to name.

C.04.218. No person shall sell an antitoxin or antiserum unless both the inner and the outer labels carry a statement of the species of animal used, when other than the horse, and the net contents in millilitres or the number of units in the container.

C.04.219. In respect of antitoxins, the expiration date shall be

(a) for liquid antitoxins with standards of potency, not later than 5 years after the date of manufacture,
(b) for dried antitoxins with standards of potency, not later than 5 years after the date of manufacture,
(c) for liquid antitoxins with no standards of potency, not later than 12 months after the date of manufacture,
15-5-68 (d) for dried antitoxins with no standards of potency, not later than 5 years after the date of manufacture.

C.04.220. In respect of antisera, the expiration date shall be

(a) for liquid antisera with standards of potency, not later than 3 years after the date of manufacture,
(b) for dried antisera with standards of potency, not later than 5 years after the date of manufacture,
(c) for liquid antisera with no standards of potency, not later than 12 months after the date of manufacture,
(d) for dried antisera with no standards of potency, not later than 5 years after the date of manufacture.

Preparations from Human Sources

C.04.230. Preparations from human sources shall be pooled blood plasma, or pooled blood serum, or fractions of either separated by a method satisfactory to the Minister.

C.04.231. A fabricator shall obtain human serum, or human plasma, only from a person certified by a qualified medical practitioner to be healthy.

C.04.232. A fabricator shall not use a person to serve as a donor of blood, placenta, or cord who has a history of a disease transmissible by blood transfusion including syphilis, infectious hepatitis or malaria.

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C.04.233. The operation of drawing blood from a donor shall be under the supervision of a qualified medical practitioner, and shall be carried out in a suitable bleeding room under the control of the fabricator.

C.04.234. A fabricator shall obtain human placenta and cord used in the manufacture of preparations from human sources only from women confined in public hospitals, and the donor of such placenta and cord shall have been free from the toxaemias of pregnancy, and the placenta and cord shall not show gross evidence of any pathological condition.

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C.04.235. (1) Subject to subsections (2) and (3), dried human serum, dried human plasma or dried fraction of either shall not contain more than one per cent moisture when determined by an acceptable method.

(2) Dried RHo(D) Immune Human globulin shall not contain more than 3 per cent moisture when determined by an acceptable method.

(3) Dried Antihemophilic Factor Human shall not contain more than 2 per cent moisture when determined by an acceptable method.

19-12-96

C.04.236. A fabricator shall provide directions or means for the removal of particles of such size as to be dangerous to the recipient from preparations from human sources that are issued in fluid form or that are reconstituted from the dried form.

C.04.237. A fabricator of preparations from human sources shall maintain complete records of all donors, which records shall include the medical certificate required by C.04.231.

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C.04.238. A fabricator, packager/labeller or distributor referred to in paragraph C.01A.003(b) may issue human serum or human plasma, or fractions of either of them, for prophylactic or therapeutic use in any of the following forms:

(a) immune human serum, which shall be serum separated from the blood of persons recovered from the disease or from persons specifically immunized against the disease, for which the serum is intended as a prophylactic or therapeutic agent,
(b) immune human globulins, or other immune human serum fractions, which shall be prepared from immune human serum or plasma,
(c) normal human serum, or normal human plasma, or fractions of either of these prepared from the blood of normal individuals, and
(d) dried products prepared from any of these.

C.04.239. No person shall sell a preparation from human sources unless both the inner and the outer labels clearly indicate that the preparation is derived from human sources.

C.04.240. The expiration date for preparations from human sources issued in fluid or dried form shall be not later than 5 years after the date of filling the immediate container.

23-4-81

C.04.300 and **C.04.301** are revoked by P.C. 1981-1125 of April 23, 1981.

Interpretation

C.04.400. The following definitions apply in this section and in sections C.04.401 to C.04.423.

"**accident**" means an unexpected event that is not attributable to a deviation from a fabricator's procedures or applicable laws and that could adversely affect the safety of a donor or the safety, efficacy or quality of plasma. (*accident*)
"**donor**" means a person aged 17 years or older who has given their name to a fabricator for the purpose of participating in plasmapheresis with that fabricator. (*donneur*)
"**error**" means a deviation from a fabricator's procedures or applicable laws that could adversely affect the safety of a donor or the safety, efficacy or quality of plasma. (*manquement*)
"**fabricator**" means a person who is the holder of an establishment licence issued under these Regulations that authorizes the person to fabricate source plasma. (*manufacturier*)
"**personal identifier**" means a unique group of letters, numbers or symbols, or any combination of them, that is assigned to a donor by a fabricator. (*identificateur personnel*)
"**physician**" means a person who is entitled to practise the profession of medicine under the laws of the province in which the person provides medical service in connection with plasmapheresis or specific immunization. (*médecin*)
"**physician substitute**" means a person who
(a) acts under the general supervision and direction of a physician; and
(b) is authorized to provide the services that may be provided by a physician substitute under sections C.04.401 to C.04.423, according to the applicable laws of the province in which the person provides any of those services. (*substitut*)
"**plasmapheresis**" means a process during which:
(a) blood is taken from a donor from which plasma is separated; and
(b) red blood cells and formed elements from the blood are returned to the donor. (*plasmaphérèse*)
"**plasmapheresis session**" means a meeting between a fabricator and a donor held for the purpose of proceeding with plasmapheresis. (*séance de plasmaphérèse*)
"**serious adverse reaction**" means an unexpected and undesirable response in a donor, associated with plasmapheresis or specific immunization, that results in any of the following consequences for the donor:
(a) hospitalization;
(b) persistent or significant disability or incapacity;
14-12-06 (c) a medical or surgical intervention to preclude a persistent or significant disability or incapacity;
(d) a life-threatening condition; or
(e) death. (*effet indésirable grave*)
"**source plasma**" means human plasma collected by plasmapheresis that is intended for use in producing a drug for human use. (*plasma destiné au fractionnement*)
"**specific immunization**" means the administration of an immunogen to a donor with the intention of eliciting an immune response in their blood for the purpose of plasmapheresis. (*immunisation spécifique*)
"**unique identifier**" means a unique group of letters, numbers or symbols, or any combination of them, that is assigned by a fabricator to source plasma or red blood cells to be used in specific immunization. (*identificateur unique*)

Prohibitions

C.04.401. No person shall

(a) sell source plasma unless it has been fabricated, tested, packaged/labelled and stored in accordance with sections C.04.402 to C.04.423; or
(b) fabricate source plasma from blood collected from a person who is not suitable to participate in plasmapheresis according to sections C.04.402 to C.04.423.

Fabricator's Responsibility

C.04.402. (1) A fabricator shall ensure that a person who provides services to them in connection with plasmapheresis or specific immunization is qualified by education and by training or experience to provide the services.

(2) The fabricator shall ensure that the premises used for donor screening, plasmapheresis or specific immunization are designed, constructed and maintained in a manner that permits medical information to be communicated in confidence.

Consent and Preliminary Evaluation

C.04.403. (1) A fabricator shall not begin plasmapheresis with a donor unless

(a) the fabricator has informed the donor of what is involved with plasmapheresis, including the risks to the donor's health associated with plasmapheresis and with participating in plasmapheresis more frequently than once every eight weeks; and
(b) after paragraph (a) has been satisfied, the fabricator obtains from the donor
  (i) a written acknowledgement that the information specified in paragraph (a) has been provided to them, and
  (ii) in accordance with the applicable laws governing consent, written informed consent to participate in plasmapheresis.

(2) A fabricator shall not begin the specific immunization of a donor unless

(a) a physician has selected the immunogen to be administered to the donor and informed the donor of
  (i) the name and nature of the selected immunogen,
  (ii) the proposed frequency and the maximum number of specific immunization injections the donor is expected to receive, and
  (iii) what is involved with specific immunization, including the risks to the donor's health associated with specific immunization and with receiving the selected immunogen; and
(b) after paragraph (a) has been satisfied, the fabricator obtains from the donor
  (i) a written acknowledgement that the information specified in paragraph (a) has been provided to them, and
  (ii) in accordance with the applicable laws governing consent, written informed consent to receive the selected immunogen.

C.04.404. (1) A fabricator shall not proceed with plasmapheresis or specific immunization unless a physician or physician substitute has determined the donor's suitability to participate in plasmapheresis more frequently than once every eight weeks based on the donor's medical history and a medical examination of the donor.

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(2) If the donor is determined to be suitable, the fabricator shall document the following information:

(a) the fact that the donor is suitable to participate in plasmapheresis more frequently than once every eight weeks;
(b) the donor's name and personal identifier;
(c) the name and signature of the physician who makes the determination, or supervises the physician substitute making the determination; and
(d) the date of the determination.

(3) The fabricator shall not proceed with plasmapheresis or specific immunization if the most recent determination under subsection (1) in respect of the donor was made more than

(a) 30 days before the date set for the donor's first participation in plasmapheresis or specific immunization; or
(b) one year before any other date set for the donor's participation in plasmapheresis or specific immunization.

Specific Immunization

C.04.405. (1) No one other than a physician or physician substitute shall administer an immunogen to a donor for the purpose of specific immunization.

(2) A physician shall monitor the donor's response to the immunogen to determine if the donor can continue to receive specific immunization.

(3) If the donor cannot continue to receive specific immunization, the fabricator shall cease to provide it to the donor until a physician determines that the donor can receive specific immunization using the same or another immunogen.

Evaluation Before Collection

C.04.406. (1) At the beginning of each plasmapheresis session, a physician or physician substitute shall determine if the donor is suitable to participate in plasmapheresis.

(2) If the donor is determined to be temporarily not suitable to participate in plasmapheresis based on the criteria set out in Table 1 or any other medical reason justifying a determination of temporary non-suitability, the fabricator shall cancel the session, inform the donor of the reason why they are temporarily not suitable and indicate the date when the donor may continue to participate in plasmapheresis.

(3) If the donor is determined to be not suitable to participate in plasmapheresis for an indefinite period based on the exclusion criteria set out in Table 2 or any other medical reason justifying a determination of indefinite non-suitability, the fabricator shall cancel the session and inform the donor of the reason why they are not suitable to participate in plasmapheresis for an indefinite period.

TABLE 1

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Item	Criteria
1.	Weight of less than 50 kg
2.	Temperature outside of normal limits
3.	Blood pressure above 100 mmHg diastolic or 180 mmHg systolic
4.	Haemoglobin level of less than 125 g/L of blood or haematocrit value of less than 0.38 L/L of blood
5.	Total protein level of less than 60 g/L of blood
6.	Substantial blood loss
7.	Prior donation of plasma or other blood components
8.	Pregnancy
9.	History of medical or surgical procedures
10.	History of convulsions requiring medical treatment
11.	Ability to answer questions compromised by alcohol or drug use
12.	Prior transfusion of blood, blood components or a blood product, or prior transplantation of a cell, tissue or organ other than dura mater
13.	Skin infection at the site of the phlebotomy
14.	Sign or symptom of infection
15.	Risk of infection with HIV, hepatitis B virus or hepatitis C virus based on, but not limited to, a history of acupuncture, skin piercing, tattooing, accidental needle-stick injury or occasional sexual relations with a person at risk of having any of those infections
16.	Current or past use of medication that poses a risk to a recipient of a product manufactured from source plasma
17.	Receipt of a live attenuated vaccine
18.	Animal bite requiring prophylaxis for rabies or for which the need for post-exposure prophylaxis has not been assessed

TABLE 2

Item	Exclusion Criteria
1.	Abnormal cardiovascular function or serious or chronic cardiovascular disease
2.	Abnormal respiratory function or serious or chronic respiratory disease
3.	Bleeding disorder that poses a risk to the donor in relation to plasmapheresis
4.	Serious disease or medical condition of the liver, kidneys, another organ, a system or blood
5.	Persistent abnormal plasma proteins including monoclonal or polyclonal gammopathy
6.	Current or past use of medication that poses an ongoing risk to a recipient of a product manufactured from source plasma
7.	History of recurrent fainting associated with the donation of blood or plasma
8.	History, signs or symptoms of injectable drug abuse such as skin punctures, scars or sharing needles to inject drugs
9.	History, signs or symptoms of AIDS or HIV infection
10.	Risk of HIV infection based on sexual practices
11.	History, signs or symptoms of a chronic or persistent infection or parasitic disease transmissible by blood
12.	History, signs or symptoms of hepatitis, other than hepatitis A
13.	Cancer, other than non-melanoma skin cancer or in-situ cervical cancer
14.	Risk factor for Creutzfeldt-Jacob disease (CJD) or its variant (vCJD) based on, but not limited to, the receipt of dura mater transplant or a treatment using a human pituitary hormone
15.	Positive test result for any transmissible disease agent

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Plasma Protein Composition

C.04.407. (1) Before beginning plasmapheresis with a donor, a fabricator shall take a blood sample from the donor to determine the plasma protein composition of the donor's blood by means of a serum protein electrophoresis test or an equivalent test.

(2) A blood sample shall be taken within seven days before the donor's first plasmapheresis session at which the fabricator proceeds with plasmapheresis.

(3) If 21 days have elapsed from the taking of the sample without a physician examining the test result, the fabricator may not proceed with plasmapheresis until a physician examines the test result.

(4) If a physician concludes that the plasma protein composition of the donor's blood is not within normal limits, the fabricator may not proceed with plasmapheresis until a physician determines that the plasma protein composition of the donor's blood is within normal limits.

(5) If the fabricator has not taken a blood sample from the donor as required under subsection (1) for more than four months, the fabricator may not proceed with plasmapheresis until the blood sample is taken from the donor.

Ongoing Review of Collection Records

C.04.408. (1) A physician shall determine if a donor is suitable to continue to participate in plasmapheresis more frequently than once every eight weeks, based on the test results and collection records for the donor that have been made or received by the fabricator within the preceding four months.

(2) The determination shall be made at least every four months after the date of the initial determination that the donor is suitable under section C.04.404.

(3) If the donor is determined to be temporarily not suitable to participate in plasmapheresis the fabricator shall inform the donor of the reason why they are temporarily not suitable and indicate the date when the donor may continue to participate in plasmapheresis.

(4) If the donor is determined to be not suitable for an indefinite period, the fabricator may not proceed with plasmapheresis and shall inform the donor of the reason why they are not suitable.

(5) If the requirement of subsection (2) is not met, the fabricator may not proceed with plasmapheresis until the determination is made.

Plasmapheresis Procedures

C.04.409. A fabricator who conducts a plasmapheresis session shall

(a) use aseptic methods and a sterile collection system licensed under the *Medical Devices Regulations*;
(b) ensure that all surfaces intended to come into contact with blood or plasma are pyrogen free;
(c) ensure that the donor's skin where the phlebotomy is to be made is
  (i) determined to be free from lesion, rash or other source of infection, and
  (ii) cleaned and disinfected; and
(d) ensure that emergency medical personnel are capable of attending to the medical needs of the donor within 10 minutes after being contacted by the fabricator.

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Maximum Volumes and Minimum Intervals

C.04.410. (1) A fabricator shall not collect plasma from a donor in a total amount, excluding anticoagulant solution, that exceeds

(a) if the donor's weight is 50 kg or more but less than 68 kg,
  (i) 625 mL or 640 g in respect of a single plasmapheresis session, and
  (ii) 11.5 L in respect of all plasmapheresis sessions during the preceding six months;
(b) if the donor's weight is 68 kg or more but less than 80 kg,
  (i) 750 mL or 770 g in respect of a single plasmapheresis session, and
  (ii) 15.5 L in respect of all plasmapheresis sessions during the preceding six months; and
(c) if the donor's weight is 80 kg or more,
  (i) 800 Ml or 820 g in respect of a single plasmapheresis session, and
  (ii) 18.5 L in respect of all plasmapheresis sessions during the preceding six months.

(2) The fabricator shall have written procedures that describe

(a) the minimum waiting period for a donor between donations of plasma and between a donation of plasma and a donation of blood or other blood components; and
(b) the maximum number of plasma donations a donor may make in a given period.

Anticoagulant Solution

C.04.411. (1) During plasmapheresis, the fabricator shall mix an anticoagulant solution with the blood collected from the donor.

(2) The anticoagulant solution shall have a valid drug identification number under these Regulations that indicates the solution is suitable for use in plasmapheresis.

Samples for Testing

C.04.412. (1) During a plasmapheresis session, the fabricator shall take a sample of blood or plasma in a manner that does not contaminate the sample or the source plasma.

(2) When the sample is taken, the fabricator shall clearly and permanently label the sample container with the unique identifier assigned to the source plasma.

(3) The fabricator shall ensure that the person who labels the sample container is the same person who labels the container holding the source plasma under subsection C.04.416(2).

C.04.413. (1) The fabricator shall test a sample taken under section C.04.412 to detect evidence of the following disease agents:

(a) HIV types 1 and 2;
(b) hepatitis B virus;
(c) hepatitis C virus; and
(d) syphillis.

(2) The fabricator shall retain the source plasma collected at the plasmapheresis session until all the test results are determined to be negative or non-reactive.

(3) In the case of a positive or reactive test result for any disease agent referred to in subsection (1), the fabricator shall

(a) clearly and permanently label the container holding the source plasma collected at the session with
  (i) the statement "Caution: Not for Manufacturing Use" or "Précaution : Non destiné à la fabrication", and
  (ii) the hazard symbol for Biohazardous Infectious Material set out in Schedule II to the *Controlled Products Regulations*; and

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(b) segregate and dispose of the source plasma.

(4) In the case of a positive or reactive test result for syphilis, the fabricator may not proceed with plasmapheresis until a subsequent test shows that the donor is not infected with syphilis and a physician determines that the donor can continue to participate in plasmapheresis.

(5) In the case of a positive or reactive test result for a disease agent referred to in subsection (1), other than syphilis, the fabricator shall discontinue plasmapheresis and inform the donor of the reason why they are not suitable to participate in plasmapheresis for an indefinite period.

Preservatives and Additives

C.04.414. No person shall add a preservative or additive to source plasma.

Containers

C.04.415. A fabricator shall place source plasma in a container

(a) in respect of which a medical device licence has been issued under the *Medical Devices Regulations* for the purpose of collecting and storing plasma;
(b) that permits visual, electronic or automated inspection of the plasma;
(c) that has been visually inspected at the plasmapheresis session and found to be intact; and
(d) that has not been previously used for any purpose, including holding source plasma from the same donor.

Labelling

C.04.416. (1) Sections C.01.004 and C.04.019 do not apply to source plasma.

(2) A fabricator shall clearly and permanently label the container used to hold source plasma with

(a) the unique identifier assigned to the source plasma in the container;
(b) the statement "Source Plasma" or "Plasma destiné au fractionnement";
(c) the statement "Caution: For Manufacturing Use Only" or "Précaution : À utiliser uniquement pour la fabrication";
(d) the quantity of the source plasma;
(e) the name and quantity of the anticoagulant solution used during the plasmapheresis;
(f) the expiry date of the source plasma, expressed in an unambiguous format;
(g) subject to subsection C.04.413(3), a statement indicating that the source plasma tests negative for the disease agents for HIV, hepatitis B and hepatitis C;
(h) if the source plasma was collected from a donor who has received specific immunization, a statement indicating the immunogen that was used;
(i) the name, address and establishment licence number of the fabricator; and
(j) a statement indicating that the source plasma must be stored at a temperature of -20°C or colder.

(3) The unique identifier shall be placed on the container at the time of collection.

Storage

C.04.417. (1) In respect of the storage of source plasma, including storage during transportation, a fabricator shall ensure that the storage environment

(a) is designed to maintain a temperature of -20°C or colder; and
(b) remains consistently at a temperature of -20°C or colder.

(2) If the temperature of the environment rises above -20°C, the fabricator shall record the following information:

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(a) the reason for the elevated temperature;
(b) the source plasma affected; and
(c) the final disposition of the source plasma.

(3) If the temperature of the environment rises to between -20°C and +10°C, the fabricator shall clearly and permanently label the container of the source plasma with the statement "Source Plasma – Salvaged" or "Plasma destiné au fractionnement – recyclé".

(4) Subsection (3) does not apply if the temperature of the environment rises to between -20°C and -5°C for a single period lasting less than 72 hours.

(5) If the temperature of the environment rises above +10°C, the fabricator shall dispose of the source plasma.

(6) Paragraph (1)(b) and subsections (2) to (5) do not apply in respect of the storage of source plasma during transportation, if the transportation is not conducted by the fabricator.

C.04.418. (1) A fabricator shall inspect each container of source plasma to determine if the container and its label are intact and if there are any indications that the source plasma has been subject to thawing.

(2) The fabricator shall dispose of the source plasma if the inspection shows that

(a) the container is defective or damaged to the extent that it does not provide protection against external factors that could result in deterioration or contamination of the source plasma;
(b) the unique identifier assigned to the source plasma is missing or illegible;
(c) any information required under paragraphs C.04.416(2)(b) to (i) is missing or illegible, unless the missing or illegible information can be retrieved from the fabricator's records; or
(d) the source plasma has been subject to thawing.

Records

C.04.419. (1) A fabricator shall use and maintain a record-keeping system according to which the fabricator shall

(a) assign a personal identifier to each donor;
(b) keep on the donor's file a photograph of the donor or some other reliable means of identification; and
(c) assign a unique identifier to the source plasma collected by the fabricator at each plasmapheresis session.

(2) The system shall be structured so that a fabricator may, based on a personal identifier or a unique identifier, identify the donor and retrieve sufficient records to permit the traceability and recall of source plasma.

(3) The fabricator shall keep the records referred to in subsection (2) indefinitely.

C.04.420. (1) For each donor, the fabricator shall keep

(a) the original or a copy of the donor's acknowledgement and consent under paragraphs C.04.403(1)(b) and (2)(b), if any;
(b) the original or a copy of any determinations, examinations, test results, reports and written notices made under sections C.04.401 to C.04.423;
(c) for each specific immunization given by the fabricator to the donor, a record indicating
  (i) the date and location of the immunization,
  (ii) the physician or physician substitute who administered the immunogen, and
  (iii) for the immunogen injected, its name and manufacturer's name, the quantity and expiry date and either the immunogen's lot number and drug identification number or, if the immunogen is red blood cells, its unique identifier;
(d) for each plasmapheresis session held by the fabricator for the donor, a record indicating
  (i) the date and location of the session,
  (ii) the volume of source plasma collected,
  (iii) the unique identifier assigned to the source plasma,
  (iv) the volume of red blood cells collected that was not returned to the donor, including the volume of red blood cells collected during sampling,
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  (v) for the anticoagulant solution used, its name, its manufacturer's name and its lot number and drug identification number, and
  (vi) for the container used, the manufacturer's name and the container's lot number and expiry date.

(2) The fabricator shall maintain a summary of all accidents, errors, serious adverse reactions and recalls of source plasma involving the fabricator.

(3) The fabricator shall maintain temperature records made under subsection C.04.417(2).

Information to the Minister

C.04.421. (1) A fabricator shall notify the Minister of any serious adverse reaction

(a) within 24 hours after the fabricator becomes aware of the occurrence, in the case of a fatality; and
(b) within 15 days after the fabricator becomes aware of the occurrence, in any other case.

(2) In the case of a verbal notice under subsection (1), the fabricator shall submit a written report of the serious adverse reaction to the Minister within 24 hours after submitting the notice.

(3) The notice, if in writing, or the written report shall include a description of the serious adverse reaction and any steps taken to address it.

C.04.422. If a fabricator recalls source plasma for a reason involving product safety, the fabricator shall provide the Minister with a written report stating the reason for the recall, the number of units involved and the location from which the units were recalled.

C.04.423. In order to prevent injury to the health and safety of donors and recipients of products manufactured from source plasma, a fabricator shall, on request, provide the Minister with a copy of any record pertaining to plasmapheresis, specific immunization or source plasma that is required by sections C.04.401 to C.04.422 to be kept by the fabricator.

Insulin Preparations

5-8-82 **C.04.550.** (1) "Insulin" means the active principle of the pancreas that affects the metabolism of carbohydrates in the animal body and that is of value in the treatment of diabetes mellitus.

(2) The Canadian Reference Standard for insulin shall be the International Standard therefor.

(3) The insulin preparations described in these Regulations shall contain insulin to which may be added only such ingredients as are prescribed in these Regulations.

(4) The potency of an insulin preparation shall be expressed in units per cubic centimetre and each unit per cubic centimetre shall provide one International Unit of insulin per cubic centimetre.

5-8-82 **C.04.551.** No person shall sell or dispense an insulin preparation that has not been stored by him continuously at a temperature between 35° and 50°F (2° and 10°C).

5-8-82 **C.04.552.** The zinc-insulin crystals used in an insulin preparation shall contain, as determined by an acceptable method,

(a) not less than 21 International Units of insulin per milligram, and
(b) on the dry basis, not less than 0.30 per cent and not more than 0.90 per cent zinc.

Insulin Injection or Insulin

24-7-85 **C.04.553.** The insulin preparation, "Insulin injection" or "Insulin" shall be a clear colourless or almost colourless sterile solution free from turbidity and insoluble matter, prepared from insulin or zinc insulin crystals, shall have a pH of not less than 2.5 or more than 3.5, or not less than 7.0 or more than 7.8 and shall contain

(a) weight by volume,
  (i) not less than 0.1 per cent and not more than 0.25 per cent of either phenol or cresol, and
  (ii) not less than 1.4 per cent and not more than 1.8 per cent glycerin; and

(b) as determined by an acceptable method, for each 1,000 International Units of insulin,
  (i) not more than 7.0 milligrams of nitrogen for Insulin Injection prepared from zinc-insulin crystals, and not more than 8.5 milligrams of nitrogen for Insulin Injection other than that made from zinc-insulin crystals,
  (ii) not less than 0.10 milligram and not more than 0.40 milligram of zinc for Insulin Injection prepared from zinc-insulin crystals, and not more than 0.40 milligram of zinc for Insulin Injection other than that made from zinc-insulin crystals, and
  (iii) in the case of Insulin Injection other than that made from zinc-insulin crystals, not more than 1.0 milligram of ash.

5-8-82 **C.04.554.** No person shall sell Insulin Injection unless,

(a) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres;
(b) the vial label indicates that each cubic centimetre has a potency equal to
  (i) 40 International Units of insulin,
  (ii) 80 International Units of insulin, or
  (iii) 100 International Units of insulin; and
(c) each cubic centimetre thereof has an actual potency that is at least 95 per cent and does not exceed 105 per cent of the potency indicated on the label as determined by an acceptable method.

19-12-96 **C.04.555.** (1) A fabricator shall not sell Insulin Injection unless he

5-8-82 (a) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;
(b) has furnished the Director with such additional information as the Director may require; and
26-4-95 (c) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(a) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Insulin Injection
  (i) protocols of assay of its potency expressed in International Units per cubic centimetre, in the case of insulin, and in International Units per milligram, in the case of zinc-insulin crystals,
5-8-82 (ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals,
  (iii) a report of the ash content in the case of insulin, and
  (iv) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin;
(b) for the first finished lot of Insulin Injection prepared from each master lot of insulin or zinc-insulin crystals, a report on the amount of each component thereof; and
(c) for the first filling of the first finished lot of Insulin Injection from each master lot of insulin or zinc-insulin crystals,
26-4-95 (i) a report of assay of its nitrogen content in milligrams per 1,000 International Units of insulin,
  (ii) a report of assay of its zinc content in milligrams per 1,000 International Units of insulin, and
  (iii) a report on the determination of its pH.

19-12-96 **C.04.556.** The expiration date printed on the inner and outer labels of every package of Insulin Injection shal be a date not later than two years after the date of removal for distribution from the fabricator's place of storage.

Insulin Zinc Suspension -- Rapid

24-7-85 **C.04.557.** The insulin preparation "Insulin Zinc Suspension--Rapid" shall be a sterile suspension in a buffered aqueous medium, of insulin modified by the addition of zinc in such a way that the suspended precipitate consists of amorphous material, shall have a pH of not less than 7.0 and not more than 7.8 and shall contain

(a) weight by volume,
  (i) not less than 0.15 per cent and not more than 0.17 per cent of sodium acetate (NaC2H3O 23H2O),
  (ii) not less than 0.65 per cent and not more than 0.75 per cent of sodium chloride, and
  (iii) not less than 0.09 per cent and not more than 0.11 per cent of methyl-p-hydroxybenzoate; and

(b) as determined by an acceptable method, for each 1,000 International Units of insulin,
10-7-80 (i) not more than 7.0 milligrams of nitrogen; and
  (ii) not less than 1.2 milligrams and not more than 2.5 milligrams of zinc, of which not less than 20 per cent and not more than 65 per cent shall be in the supernatant liquid.

5-8-82 **C.04.558.** The insulin used in the preparation of Insulin Zinc Suspension--Rapid shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of Insulin Zinc Suspension--Rapid when the precipitate is suspended uniformly.

5-8-82 **C.04.559.** The clear supernatant liquid obtained from Insulin Zinc Suspension--Rapid shall contain not more than 1.0 International Unit of insulin per cubic centimetre when the potency of the insulin preparation is 40 units per cubic centimetre, and not more than 1.5 International Units of insulin per cubic centimetre when the potency of the insulin preparation is either 80 units or 100 units per cubic centimetre, as determined by an acceptable method.

5-8-82 **C.04.560.** No person shall sell Insulin Zinc Suspension--Rapid unless

(a) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and
(b) each cubic centimetre thereof provides, when the precipitate is suspended uniformly,
  (i) 40 International Units of insulin,
  (ii) 80 International Units of insulin, or
8-1-74 (iii) 100 International Units of insulin.

19-12-96 **C.04.561.** (1) A fabricator shall not sell Insulin Zinc Suspension--Rapid unless he

(a) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;
(b) has furnished the Director such additional information as the Director may require; and
26-4-95 (c) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(a) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Insulin Zinc Suspension--Rapid,
(i) protocols of assay of its potency expressed in International Units per cubic centimetre in the case of insulin, and in International Units per milligram in the case of zinc-insulin crystals,
(ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals, and
5-8-82 (iii) reports of assay of its nitrogen content in milligram and its zinc content in milligrams per 1,000 International Units of insulin;

(b) for the first finished lot of Insulin Zinc Suspension--Rapid prepared from each master lot of insulin or zinc-insulin crystals
(i) a report on the amount of each component used in the preparation,
(ii) a report of assay of its nitrogen content per 1,000 International Units of insulin,
(iii) a report of assay of its zinc content per 1,000 International Units of insulin,
(iv) a report of the insulin content in International Units per cubic centimetre of the supernatant liquid after removal of the suspended precipitate,
(v) a report of assay of the zinc content of the supernatant liquid after removal of the suspended precipitate,
(vi) a report on the determination of its pH, and
(vii) a report on the microscopic appearance of the suspended precipitate; and

(c) for the first filling of the first finished lot of Insulin Zinc Suspension--Rapid from each master lot of insulin or zinc-insulin crystals,
26-4-95 (i) a report on the determination of its pH,
(ii) a report on the microscopic examination of the precipitate, and
(iii) a report on its identification, as determined by an acceptable method.

5-8-82 **C.04.562.** The expiration date printed on the inner and outer labels of every package of Insulin Zinc Suspension--Rapid shall be a date not later than two years after the date of filling of the immediate container.

Insulin Zinc Suspension -- Medium

24-7-85 **C.04.563.** The insulin preparation "Insulin Zinc Suspension--Medium" shall be a sterile suspension, in a buffered aqueous medium, of insulin modified by the addition of zinc in such a way that the suspended precipitate consists of a mixture of crystals and amorphous material in an approximate ratio of seven parts of crystals to three parts of amorphous material, shall have a pH of not less than 7.0 and not more than 7.8 and shall contain

(a) weight by volume,
(i) not less than 0.15 per cent and not more than 0.17 per cent of sodium acetate (NaC2H3O 23H2O),
(ii) not less than 0.65 per cent and not more than 0.75 per cent of sodium chloride, and
(iii) not less than 0.09 per cent and not more than 0.11 per cent of methyl-p-hydroxybenzoate; and

(b) as determined by an acceptable method, for each 1,000 International Units of insulin,
16-6-88 (i) not more than 7.0 milligrams of nitrogen of which not less than 63 per cent and not more than 73 per cent shall be in the crystalline component, and
10-7-80 (ii) not less than 1.2 milligrams and not more than 2.5 milligrams of zinc, of which not less than 20 per cent and not more than 65 per cent shall be in the supernatant liquid.

5-8-82 **C.04.564.** The insulin used in the preparation of Insulin Zinc Suspension--Medium shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of the preparation when the precipitate is suspended uniformly.

5-8-82 **C.04.565.** The clear supernatant liquid obtained from Insulin Zinc Suspension--Medium shall contain not more than 1.0 International Unit of insulin per cubic centimetre when the potency of the insulin preparation is 40 units per cubic centimetre, and not more than 1.5 International Units of insulin per cubic centimetre when the potency of the insulin preparation is either 80 units or 100 units per cubic centimetre, as determined by an acceptable method.

5-8-82 **C.04.566.** No person shall sell Insulin Zinc Suspension--Medium unless

(a) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and

(b) each cubic centimetre thereof provides, when the precipitate is suspended uniformly,

(i) 40 International Units of insulin,

(ii) 80 International Units of insulin, or

8-1-74 (iii) 100 International Units of insulin.

19-12-96 **C.04.567.** (1) A fabricator shall not sell Insulin Zinc Suspension--Medium unless he

(a) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(b) has furnished the Director with such additional information as the Director may require; and

26-4-95 (c) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(a) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Insulin Zinc Suspension--Medium,

(i) protocols of assay of its potency expressed in International Units per cubic centimetre in the case of insulin, and in International Units per milligram in the case of zinc-insulin crystals,

(ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals, and

(iii) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin;

5-8-82 (b) for the first finished lot of Insulin Zinc Suspension--Medium prepared from each master lot of insulin or zinc-insulin crystals,

(i) a report on the amount of each component used in the preparation,

(ii) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(iii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(iv) a report of the insulin content, in International Units per cubic centimetre, of the supernatant liquid after removal of the suspended precipitate,

(v) a report on the determination of the proportion of the nitrogen in the crystalline component of the suspended precipitate,

(vi) a report of assay of the zinc content of the supernatant liquid after removal of the suspended precipitate,

(vii) a report on the determination of its pH, and

(viii) a report on the microscopic appearance of the suspended precipitate; and

(c) for the first filling of the first finished lot of Insulin Zinc Suspension--Medium from each master lot of insulin or zinc-insulin crystals,

26-4-95 (i) a report on the determination of its pH,

(ii) a report on the microscopic examination of the precipitate, and

(iii) a report on its identification as determined by an acceptable method.

5-8-82 **C.04.568.** The expiration date printed on the inner and outer labels of Insulin Zinc Suspension--Medium shall be a date not later than two years after the date of filling of the immediate container.

Insulin Zinc Suspension -- Prolonged

24-7-85 **C.04.569.** The insulin preparation "Insulin Zinc Suspension--Prolonged" shall be a sterile suspension in a buffered aqueous medium of insulin modified by the addition of zinc in such a way that the suspended precipitate consists of crystals with not more than a trace of amorphous material, shall have a pH of not less than 7.0 and not more than 7.8 and shall contain

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16-2-67 (a) weight by volume,
(i) not less than 0.15 per cent and not more than 0.17 per cent of sodium acetate ($NaC_2H_3O_2 3H_2O$),
(ii) not less than 0.65 per cent and not more than 0.75 per cent of sodium chloride, and
(iii) not less than 0.09 per cent and not more than 0.11 per cent of methyl-**p**-hydroxybenzoate; and

(b) as determined by an acceptable method, for each 1,000 International Units of insulin,
(i) not more than 7.0 milligrams of nitrogen, of which not less than 90 per cent shall be in the crystalline component, and
10-7-80 (ii) not less than 1.2 milligrams and not more than 2.5 milligrams of zinc, of which not less than 20 per cent and not more than 65 per cent shall be in the supernatant liquid.

5-8-82 **C.04.570.** The insulin used in the preparation of Insulin Zinc Suspension--Prolonged shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of the preparation when the precipitate is suspended uniformly.

5-8-82 **C.04.571.** The clear supernatant liquid obtained from Insulin Zinc Suspension--Prolonged shall contain not more than 1.0 International Unit of insulin per cubic centimetre when the potency of the insulin preparation is 40 units per cubic centimetre, and not more than 1.5 International Units of insulin per cubic centimetre when the potency of the insulin preparation is either 80 units or 100 units per cubic centimetre, as determined by an acceptable method.

5-8-82 **C.04.572.** No person shall sell Insulin Zinc Suspension--Prolonged unless

(a) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and
(b) each cubic centimetre thereof provides, when the precipitate is suspended uniformly,
(i) 40 International Units of insulin,
(ii) 80 International Units of insulin, or
8-1-74 (iii) 100 International Units of insulin.

19-12-96 **C.04.573.** (1) A fabricator shall not sell Insulin Zinc Suspension--Prolonged unless he

(a) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;
(b) has furnished the Director with such additional information as the Director may require; and
26-4-95 (c) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(a) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Insulin Zinc Suspension--Prolonged,
(i) protocols of assay of its potency expressed in International Units per cubic centimetre in the case of insulin, and in International Units per milligram in the case of zinc-insulin crystals,
(ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals, and
(iii) reports of assay of the nitrogen content in milligrams and of its zinc content in milligrams per 1,000 International Units of insulin;
5-8-82 (b) for the first finished lot of Insulin Zinc Suspension--Prolonged prepared from each master lot of insulin or zinc-insulin crystals,
(i) a report on the amount of each component used in the preparation,
(ii) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,
(iii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,
(iv) a report of the insulin content, in International Units per cubic centimetre, of the supernatant liquid after removal of the suspended precipitate,
(v) a report of the determination of the proportion of the nitrogen in the crystalline component of the suspended precipitate,
(vi) a report of assay of the zinc content of the supernatant liquid after removal of the suspended precipitate,
(vii) a report on the determination of its pH, and
(viii) a report on the microscopic appearance of the suspended precipitate; and

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(c) for the first filling of the first finished lot of Insulin Zinc Suspension--Prolonged from each master lot of insulin or zinc-insulin crystals,

26-5-95 (i) a report on the determination of its pH,

(ii) a report on the microscopic examination of the precipitate, and

(iii) a report on its identification as determined by an acceptable method.

5-8-82 **C.04.574.** The expiration date printed on the inner and outer labels of every package of Insulin Zinc Suspension--Prolonged shall be a date not later than two years after the date of filling of the immediate container.

Globin Insulin with Zinc

C.04.575. The insulin preparation **"Globin Insulin with Zinc"** shall be a sterile solution of insulin modified by the addition of globin prepared from beef blood, in the form of globin hydrochloride, and zinc, shall be a clear, yellowish, or almost colourless liquid free from insoluble matter and acceptably free from turbidity, shall hav a pH of not less than 3.4 and not more than 3.8 and shall contain,

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(a) weight by volume, not less than 1.3 per cent and not more than 1.7 per cent glycerin, and either

(i) not less than 0.15 per cent and not more than 0.20 per cent cresol, or

(ii) not less than 0.20 per cent and not more than 0.26 per cent phenol, and

(b) as determined by an acceptable method, for each 1,000 International Units of insulin,

(i) not more than 15.0 milligrams of total nitrogen,

(ii) not less than 36.0 milligrams and not more than 40.0 milligrams of globin calculated as 6.0 times the nitrogen content of the globin, and

(iii) not less than 2.5 milligrams and not more than 3.5 milligrams of zinc.

5-8-82 **C.04.576.** The globin hydrochloride used in the preparation of Globin Insulin with Zinc shall contain not less than 16.0 per cent and not more than 17.5 per cent nitrogen calculated on a dry, ash-free and hydrochloric acid-free basis, and its ash content shall be not more than 0.3 per cent as determined by an acceptable method.

5-8-82 **C.04.577.** The insulin used in the preparation of Globin Insulin with Zinc shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40 or 80 International Units of insulin in each cubic centimetre of the Globin Insulin with Zinc.

5-8-82 **C.04.578.** (1) The Canadian Reference Standard for Globin Insulin with Zinc shall be the standard adopted therefor by the Director from time to time.

19-12-96 (2) Upon application of a person who holds an establishment licence, the Director shall furnish him with a portion of the Canadian Reference Standard with directions for comparative testing.

(3) The testing of the biological reaction of Globin Insulin with Zinc shall be made by an acceptable method and that biological reaction shall be comparable to the biological reaction of the portion of the Canadian Reference Standard furnished by the Director.

5-8-82 **C.04.579.** No person shall sell Globin Insulin with Zinc unless

(a) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and

(b) each cubic centimetre thereof provides,

(i) 40 International Units of insulin, or

(ii) 80 International Units of insulin.

19-12-96 **C.04.580.** (1) A fabricator shall not sell Globin Insulin with Zinc unless he

5-8-82 (a) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(b) has furnished the Director with such additional information as the Director may require; and

26-4-95 (c) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(a) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Globin Insulin with Zinc,
  (i) protocols of assay of its potency expressed in International Units per cubic centimetre in the case of insulin, and in International Units per milligram in the case of zinc-insulin crystals,
  (ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals, and
  (iii) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin;

(b) for the master lot of globin hydrochloride used in the preparation of Globin Insulin with Zinc, reports of assay of
  (i) its nitrogen content in per cent calculated on a dry, ash-free and hydrochloric acid-free basis,
  (ii) its chloride content in per cent calculated as hydrochloride, and
  (iii) its ash content in percentage;

5-8-82 (c) for the components used in the preparation of the trial mixture of Globin Insulin with Zinc, a report on the quantity of
  (i) insulin in grams, or in International Units,
  (ii) zinc in grams, or in milligrams, per 1,000 International Units of insulin,
  (iii) globin hydrochloride in grams or in milligrams, per 1,000 International Units of insulin, and
  (iv) the volume of the preparation in cubic centimetre or litres;

(d) for the trial mixture of Globin Insulin with Zinc,
  (i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,
  (ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,
  (iii) protocols of the biological reaction showing the retardation of the insulin effect, and
  (iv) a report on the determination of its pH;

(e) for the first finished lot of Globin Insulin with Zinc from each trial mixture of Globin Insulin with Zinc, a report on the amount of each component in the preparation; and

(f) for the first filling of the first finished lot of Globin Insulin with Zinc from each trial mixture of Globin Insulin with Zinc,
  (i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

26-4-95 (ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin, and
  (iii) a report on the determination of its pH.

5-8-82 **C.04.581.** The expiration date printed on the inner and outer labels of every package of Globin Insulin with Zinc shall be a date not later than two years after the date of filling of the immediate container.

NPH Insulin or Isophane Insulin

24-7-85 **C.04.582.** The insulin preparation "NPH Insulin" or "Isophane Insulin" shall be a sterile preparation of rod-shaped crystals containing insulin, protamine and zinc, suspended in a buffered aqueous medium, shall have a pH of not less than 7.0 and not more than 7.8 and shall contain

(a) weight by volume, not less than 0.15 per cent and not more than 0.25 per cent anhydrous disodium phosphate, and either
  (i) not less than 1.4 per cent and not more than 1.8 per cent glycerin and not less than 0.15 per cent and not more than 0.17 per cent metacresol and not less than 0.06 and not more than 0.07 per cent phenol, or
  (ii) not less than 0.40 per cent and not more than 0.45 per cent sodium chloride and not less than 0. per cent and not more than 0.9 per cent glycerin and not less than 0.18 per cent and not more than 0.22 per cent metacresol; and

(b) as determined by an acceptable method, for each 1,000 International Units of insulin,
  (i) not more than 8.5 milligrams of nitrogen,
  (ii) not less than 3.0 milligrams and not more than 6.0 milligrams of protamine except that the ratio o the protamine to the insulin shall be not less than the isophane ratio and shall not exceed the isophane ratio by more than 10 per cent, and

28-8-74 (iii) not less than 0.10 milligram and not more than 0.40 milligram of zinc, and
8-1-74 (iv) no protease activity significant for the stability of NPH Insulin.

5-8-82 **C.04.583.** The protamine used in preparing NPH Insulin shall be obtained from the sperm or from the mature testes of fish belonging to the family *Salmonidae*, genera *Oncorhynchus* Suckley, or *Salmo* Linne.

5-8-82 **C.04.584.** The "isophane ratio" means the minimum number of milligrams of protamine required to precipitate 100 International Units of insulin and shall be determined by an acceptable method.

5-8-82 **C.04.585.** The insulin used in the preparation of NPH Insulin shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of the preparation when the precipitate is suspended uniformly.

5-8-82 **C.04.586.** The clear supernatant liquid obtained from NPH Insulin shall contain not more than 0.4 International Units of insulin per cubic centimetre when the potency of the insulin preparation is 40 units per cubic centimetre, not more than 0.6 International Units of insulin per cubic centimetre when the potency of the insulin preparation is 80 units per cubic centimetre and not more than 0.7 International Units of insulin per cubic centimetre when the potency of the insulin preparation is 100 units per cubic centimetre, as determined by an acceptable method.

5-8-82 **C.04.587.** No person shall sell NPH Insulin unless

(a) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and
(b) each cubic centimetre thereof provides,
(i) 40 International Units of insulin,
(ii) 80 International Units of insulin, or
8-1-74 (iii) 100 International Units of insulin.

19-12-96 **C.04.588.** (1) A fabricator shall not sell NPH Insulin unless he
(a) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;
(b) has furnished the Director with such additional information as the Director may require; and
26-4-95 (c) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,
(a) for each master lot of zinc-insulin crystals employed in the manufacture of NPH Insulin,
(i) protocols of assay of its potency in International Units per milligram,
(ii) a report of its moisture content in per cent determined by drying to constant weight at 100°C, and
(iii) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin;
(b) for the master lot of protamine, a report of the isophane ratio for the insulin used in the preparation of the NPH Insulin;
(c) for the trial mixture of NPH Insulin,
(i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,
5-8-82 (ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,
(iii) a report of the insulin content in International Units per cubic centimetre of the supernatant liquid after removal of the suspended precipitate,
(iv) a report on the determination of its pH, and
(v) a report on the microscopic examination of the precipitate;
(d) for the first finished lot of NPH Insulin from each trial mixture of NPH Insulin, a report on the amount of each component in the preparation; and
(e) for the first filling of the first finished lot of NPH Insulin from each trial mixture of NPH Insulin,
(i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,
(ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,
(iii) a report on the determination of its pH,
26-4-95 (iv) a report on the microscopic examination of the precipitate, and
(v) a report of its identification as determined by an acceptable method.

5-8-82 **C.04.589.** The expiration date printed on the inner and outer labels of NPH Insulin shall be a date not later than two years after the date of filling of the immediate container.

Protamine Zinc Insulin

5-8-82 **C.04.590.** The insulin preparation **"Protamine Zinc Insulin"** shall be a sterile white suspension in a buffered aqueous medium, containing insulin modified by the addition of protamine and zinc, shall have a pH of not less than 7.1 and not more than 7.4, and shall contain,

(a) weight by volume
  (i) not less than 0.15 per cent and not more than 0.25 per cent anhydrous disodium phosphate,
  (ii) not less than 1.4 per cent and not more than 1.8 per cent glycerin, and
  (iii) either not less than 0.18 per cent and not more than 0.22 per cent cresol, or not less than 0.22 per cent and not more than 0.28 per cent phenol; and

(b) as determined by an acceptable method, for each 1,000 International Units of insulin,
  (i) not more than 12.5 milligrams of total nitrogen,
  (ii) not less than 10.0 milligrams and not more than 15.0 milligrams of protamine, and
16-7-74 (iii) not less than 1.7 milligrams and not more than 2.5 milligrams of zinc.

5-8-82 **C.04.591.** The protamine used in the preparation of Protamine Zinc Insulin shall be obtained from the sperm or from the mature testes of fish belonging to the family Salmonidae, genera Oncorhynchus Suckley or Salmo Linne.

5-8-82 **C.04.592.** The insulin used in the preparation of Protamine Zinc Insulin shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of the preparation when the precipitate is suspended uniformly.

5-8-82 **C.04.593.** (1) The Canadian Reference Standard for Protamine Zinc Insulin shall be the standard adopted therefor by the Director from time to time.

19-12-96 (2) Upon application of a person who holds an establishment licence, the Director shall furnish him with a portion of the Canadian Reference Standard with directions for comparative testing.

(3) The testing of the biological reaction of Protamine Zinc Insulin shall be made by an acceptable method and that biological reaction shall be comparable to the biological reaction of the portion of the Canadian Reference Standard furnished by the Director.

5-8-82 **C.04.594.** No person shall sell Protamine Zinc Insulin unless

(a) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and

(b) each cubic centimetre thereof provides
  (i) 40 International Units of insulin,
  (ii) 80 International Units of insulin, or
8-1-74 (iii) 100 International Units of insulin.

19-12-96 **C.04.595.** (1) A fabricator shall not sell Protamine Zinc Insulin unless he

5-8-82 (a) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(b) has furnished the Director with such additional information as the Director may require; and

26-4-95 (c) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(a) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Protamine Zinc Insulin,
5-8-82 (i) protocols of assay of its potency in International Units per cubic centimetre in the case of insulin and in International Units per milligram in the case of zinc-insulin crystals,
  (ii) a report on its moisture content in percentage determined by drying to constant weight at 100°C i the case of zinc-insulin crystals, and
  (iii) reports of assay of its nitrogen content in milligrams, and its zinc content in milligrams per 1,000 International Units of insulin;

(b) for the components used in the preparation of the trial mixture of Protamine Zinc Insulin, a report on the quantity of
  (i) insulin in grams or in International Units,
  (ii) zinc in grams or in milligrams, per 1,000 International Units of insulin,
  (iii) protamine in grams or in milligrams, per 1,000 International Units of insulin, and
  (iv) the volume of the preparation in cubic centimetres or litres;

(c) for the trial mixture of Protamine Zinc Insulin,
  (i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of Insulin,
5-8-82 (ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,
  (iii) protocols of its biological reaction showing retardation of the insulin effect, and
  (iv) a report on the determination of its pH;
(d) for the first finished lot of Protamine Zinc Insulin from each trail mixture of Protamine Zinc Insulin, a report on the amount of each component in the preparation; and
(e) for the first filling of the first finished lot of Protamine Zinc Insulin from each trial mixture of Protamine Zinc Insulin,
  (i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units,
26-4-95 (ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units, and
  (iii) a report on the determination of its pH.

5-8-82 **C.04.596.** The expiration date printed on the inner and outer labels of every package of Protamine Zinc Insulin shall be a date not later than two years after the date of filling of the immediate container.

Sulphated Insulin

5-8-82 **C.04.597.** The insulin preparation **"Sulphated Insulin"** shall be a clear or slightly turbid, colourless or almost colourless, sterile, isotonic preparation of zinc-insulin crystals chemically modified by treatment with sulphuric acid, shall have a pH of not less than 6.0 and not more than 7.0, and shall contain,

(a) weight by volume,
  (i) not less than 0.6 per cent and not more than 1.0 per cent sodium chloride, and
  (ii) not less than 0.2 per cent and not more than 0.3 per cent phenol; and

(b) as determined by an acceptable method,
  (i) not more than 200 milligrams protein for each 1,000 International Units of insulin, and
  (ii) not less than 5.5 and not more than 6.5 sulphate groups per insulin molecule.

5-8-82 **C.04.598.** The "neutralization ratio" means the amount of anti-beef-insulin serum required to neutralize one unit of Sulphated Insulin divided by the amount required to neutralize one unit of beef insulin, and shall be determined by an acceptable method.

5-8-82 **C.04.599.** The neutralization ratio of Sulphated Insulin shall be not less than 4 to 1.

5-8-82 **C.04.600.** No person shall sell Sulphated Insulin unless

(a) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres, and
(b) each cubic centimetre thereof provides 100 International Units of insulin as determined by an acceptable method.

19-12-96 **C.04.601.** (1) A fabricator shall not sell Sulphated Insulin unless he

5-8-82 (a) has filed with the Director, in accordance with subsection (2) a submission relating to that preparation, in a form and having a content satisfactory to the Director;
(b) has furnished the Director with such additional information as the Director may require; and
26-4-95 (c) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

5-8-82 (a) for each master lot of zinc-insulin crystals employed in the manufacture of Sulphated Insulin,
- (i) protocols of assay of its potency in International Units per milligram,
- (ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C, and
- (iii) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin; and

(b) for each lot of Sulphated Insulin prepared from each master lot of zinc-insulin crystals,
- (i) a report of the amount of each component,
- (ii) a report of the protein content in milligrams per 1,000 International Units of insulin,
- (iii) a report on the determination of the neutralization ratio,
- (iv) a report on the determination of the number of sulphate groups per insulin molecule,

26-4-95
- (v) protocols of assay of its potency expressed as International Units per cubic centimetre, and
- (vi) a report on the determination of its pH.

5-8-82 **C.04.602.** The expiration date printed on the inner and outer labels of every package of Sulphated Insulin shall be a date not later than two years after the date of filling of the immediate container.

Labelling of Insulin Preparations

19-12-96 **C.04.650.** The packager/labeller of Insulin Injection may label that insulin preparation "Insulin made from Zinc-Insulin crystals" only when it has been prepared from zinc-insulin crystals.

19-12-96 **C.04.651.** The packager/labeller of an insulin preparation shall print the information required by these Regulations to appear on both the inner and outer labels of every package of that insulin preparation as set out in the Table to this section.

TABLE

Item	Column I Insulin Preparation	Column II Potency of Preparation	Column III Special Printing Requirements for Label
1 8-1-74	Insulin Injection, not labelled as set out in item 2.	(a) 40 units per cc. (b) 80 units per cc. (c) 100 units per cc.	(a) black ink on yellow stock. (b) black ink on green stock. (c) black ink on white stock.
2 8-1-74	Insulin Injection, labelled "Insulin made from Zinc-Insulin crystals".	(a) 40 units per cc. (b) 80 units per cc. (c) 100 units per cc.	(a) red ink on grey stock. (b) green ink on grey stock. (c) black ink on white stock.
3 8-1-74	Insulin Zinc Suspension--Rapid, Insulin Zinc Suspension--Medium and Insulin Zinc Suspension--Prolonged.	(a) 40 units per cc. (b) 80 units per cc. (c) 100 units per cc.	(a) red ink on lavender stock plus a distinguishing mark or design. (b) green ink on lavender stock plus a distinguishing mark or design. (c) black ink on white stock.
4	Globin Insulin with Zinc.	(a) 40 units per cc. (b) 80 units per cc.	(a) red ink on brown stock except that the expression "40 units per cubic centimetre" may be printed in white letters on a red background. (b) green ink on brown stock except that the expression "80 units per cubic centimetre" may be printed in white letters on a green background.
5 8-1-74	NPH Insulin.	(a) 40 units per cc. (b) 80 units per cc. (c) 100 units per cc.	(a) red ink on blue stock. (b) green ink on blue stock. (c) black ink on white stock.
6 8-1-74	Protamine Zinc Insulin.	(a) 40 units per cc. (b) 80 units per cc. (c) 100 units per cc.	(a) red ink on white stock. (b) green ink on white stock. (c) black ink on white stock.
7	Sulfated Insulin.	(a) 100 units per cc.	(a) black ink on white stock plus the statement "Warning ... Not for Ordinary Use ... See Package Leaflet".

*(R) Minor correction

19-12-96 | **C.04.652.** The packager/labeller of an insulin preparation shall print on the outer label of every package thereof instructions to store the preparation in a refrigerator at 35° to 50°F (2° to 10°C) and to avoid exposing it to freezing.

19-12-96 | **C.04.653.** The packager/labeller of an insulin preparation that consists of a precipitate suspended in a buffered aqueous medium shall print on the inner label of every package thereof the statement "Shake Carefully".

19-12-96 | **C.04.654.** The packager/labeller of an insulin preparation may, in lieu of printing adequate directions for its use on both the inner and outer labels thereof as required by subparagraphs C.04.019(a)(vii), print the description for use in a descriptive circular prepared in accordance with section C.04.655, but in such case he shall

(a) enclose a copy of the circular in the package containing the preparation; and
(b) state on the outer label of the package that such a circular is enclosed therein.

5-8-82 | **C.04.655.** The descriptive circular referred to in section C.04.654 shall include, at least, the following information:

(a) a statement that
  (i) the treatment of *diabetes mellitus* requires medical supervision and review,
  (ii) insulin preparations should be used only as determined by a physician for each patient in the light of blood-sugar and urinary-sugar findings, and
  (iii) the physician's instructions concerning diet, dosage, rest and exercise should be followed carefully;

(b) an outline of the procedure to be followed in withdrawing the insulin preparation from the vial, including techniques for sterilization of the syringe and needle, vial-stopper and site of injection;
(c) a statement explaining the injections should be subcutaneous, and not intravenous or intramuscular, and a caution against successive injections in any one site;
(d) a statement that doses are specified in terms of *Units* of potency per cubic centimetre and that the *volume* of each dose will depend upon the potency in terms of units per cubic centimetre stated on the label of the insulin preparation and that, for these reasons, it is important that the patient understand the markings on syringes;
(e) a brief explanation of *hypoglycemia* together with emergency measures suitable for use by patients and those caring for patients in the event of hypoglycemic reactions;
(f) a statement indicating the possibility of undesirable reactions associated with illness or infection, with the omission or loss of a meal, and with a shortage of the insulin preparation;
(g) a statement warning against using any other type of insulin preparation than that prescribed by the physician;
(h) a statement that the use of a package should not be commenced after the expiration date printed on the package;
(i) a statement that the contents should be used as continuously as practicable and that any vial from which a part of the contents has been withdrawn should be discarded in the vent of its being in disuse for several weeks' time;
(j) a statement stressing the importance of visiting a physician regularly and of carefully following his instructions;
(k) in the case of insulin preparations consisting of a clear, colourless or almost colourless solution, free from turbidity and from insoluble matter, a statement that if the contents of the vial become cloudy or turbid, use of that vial should be discontinued;
(l) in the case of insulin preparations consisting of a precipitate suspended in a buffered aqueous medium, a statement explaining that it is necessary to shake the vial carefully before withdrawing a dose, noting that if the contents have become lumpy or granular in appearance or have formed a deposit of particles on the wall of the container, the use of that vial should be discontinued;
(m) instructions that the insulin preparation should be stored in a refrigerator at 35°-50°F (2°-10°C) and should not be exposed to freezing; and
(n) in the case of Sulphated Insulin, a statement explaining that this insulin preparation is not for ordinary use, but is a chemically modified insulin which may be more effective than the usual insulin preparations in certain insulin-resistant or insulin-allergic diabetic patients.

*(R) Minor correction

19-12-96 **C.04.656.** (1) Notwithstanding section C.04.554, a person who holds an establishment licence may sell insulin injection made from zinc-insulin crystals contained in vials of approximately 20 cubic centimetre capacity each of which vials

(a) contains an excess volume sufficient to permit withdrawal of 20 cubic centimetres, and
(b) provides 500 International Units of insulin per cubic centimetre,

if

(c) notwithstanding section C.04.651, both the inner and outer labels are printed in black ink on white stock and overprinted in narrow brown and white diagonal stripes, of which there shall be at least 5 but not more than 20 to each inch,
(d) both the inner and the outer labels carry the statement "Warning--High Potency -- Not for Ordinary Use" and
(e) each package contains a descriptive circular that conforms to the requirements of section C.04.655 and, in addition, includes,
(i) at the beginning of the circular the statement:

5-8-82 "Warning--This insulin preparation contains 500 International Units of insulin in each cubic centimetre. Extreme caution must be observed in the measurement of doses because inadvertent over-dose may result in irreversible shock. Serious consequences may result if it is used other than under constant medical supervision. Unless specifically prescribed it should never be used by patients to replace use of any other insulin preparation.",

(ii) a statement that Insulin made from Zinc-Insulin crystals 500 International Units per cubic centimetre should not be administered intravenously, and
(iii) a statement giving information for the safe and effective use by physicians of the drug in insulin shock therapy and in the treatment of diabetic patients with high insulin resistance (daily requirement more than 200 International Units of insulin).

26-5-95 (2) Revoked by P.C. 1995-664 of April 26, 1995.

Anterior Pituitary Extracts

5-8-82 **C.04.675.** Anterior pituitary extract shall include all natural products, prepared from the anterior lobe of the pituitary gland of animals, having physiological properties associated with the hormones of the anterior pituitary gland and their proper names shall be

(a) **Adrenocorticotrophic Hormone, Corticotrophin,**
(b) **Thyrotrophic Hormone, Thyrotrophin,**
(c) **Growth Hormone Pituitary, Somatotrophin,**
(d) **Lactogenic Hormone, Prolactin,**
(e) **Gonadotrophic Hormone, Gonadotrophin,** following by qualifying words to indicate gonadotrophic activity associated with the extract,

and if unpurified anterior pituitary extract

(f) **Pituitary Extract Anterior Lobe** followed by qualifying words to indicate the physiological properties associated with it.

*(R) Minor correction

5-8-82 **C.04.676.** Reference standards for anterior pituitary extract shall be

(a) the International Standard,

(b) where no International Standard exists, the Canadian Reference Standard shall be that established and kept by the Director from whom portions for comparative testing may be had upon application; and

19-12-96 (c) where neither an International Standard nor a Canadian Reference Standard exists, a provisional reference standard that shall be a suitable quantity of the product submitted by the distributor referred to in paragraph C.01A.003(b) to the Director for checking the uniformity of the product.

4-12-97 **C.04.677.** Both the inner and the outer labels of an anterior pituitary extract shall carry a statement of the potency in terms of the reference standard for anterior pituitary extract provided in section C.04.676 as determined by an acceptable method, except that where no reference standard for an anterior pituitary extract exists, the distributor referred to in paragraph C.01A.003(b) shall include, with every package of the anterior pituitary extract, an acceptable statement of the unit of potency and the method of assay used.

19-12-96 **C.04.678.** No person who holds an establishment licence shall sell corticotrophic hormones for subcutaneous or intramuscular use unless the preparation has been assayed by an acceptable method involving subcutaneous injection and, where the preparation is recommended for intravenous use, the label carries specific dosage instructions for the use.

5-8-82 **C.04.679.** No person shall sell as such adrenocorticotrophic hormone, thyrotrophic hormone, growth hormone pituitary, lactogenic hormone, or gonadotrophic hormone that is not acceptably free from any anterior pituitary extract other than the one for which it is named.

20-4-93 **C.04.680.** The outer label of a mixture of two or more of adrenocorticotrophic hormone, thyrotrophic hormone, growth hormone pituitary, lactogenic hormone and gonadotrophic hormone, or a mixture of any of those with pituitary extract anterior lobe, shall carry a declaration of the proper name and the amount of each component of the mixture.

5-8-82 **C.04.681.** The outer label of an anterior pituitary extract or mixture of anterior pituitary extracts shall carry a statement

(a) showing the species of animal from which the glands used in the preparation of the anterior pituitary extract were obtained;

(b) that it shall be stored at refrigerator temperature; and

21-12-61 (c) that, except in the case of gonadotrophic hormones, it is to be used only on the advice or on the prescription of a physician.

5-8-82 **C.04.682.** Both the inner and the outer labels of adrenocorticotrophic hormone shall carry a statement indicating the route of administration, in addition to meeting the requirements of paragraphs C.04.681 (a) and (b).

5-8-82 **C.04.683.** The expiration date for an anterior pituitary extract or mixture of anterior pituitary extracts shall be not more than two years after the date of passing a potency test.

DRUGS FOR CLINICAL TRIALS INVOLVING HUMAN SUBJECTS

Interpretation

C.05.001. The definitions in this section apply in this Division.

"**adverse drug reaction**" means any noxious and unintended response to a drug that is caused by the administration of any dose of the drug. (*réaction indésirable à une drogue*)

"**adverse event**" means any adverse occurrence in the health of a clinical trial subject who is administered a drug, that may or may not be caused by the administration of the drug, and includes an adverse drug reaction. (*incident thérapeutique*)

"**clinical trial**" means an investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug. (*essai clinique*)

"**drug**" means a drug for human use that is to be tested in a clinical trial. (*drogue*)

"**good clinical practices**" means generally accepted clinical practices that are designed to ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons, and the good clinical practices referred to in section C.05.010. (*bonnes pratiques cliniques*)

"**import**" means to import a drug into Canada for the purpose of sale in a clinical trial. (*importer*)

"**investigator's brochure**" means, in respect of a drug, a document containing the preclinical and clinical data on the drug that are described in paragraph C.05.005(e). (*brochure du chercheur*)

"**protocol**" means a document that describes the objectives, design, methodology, statistical considerations and organization of a clinical trial. (*protocole*)

"**qualified investigator**" means the person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial site is located, and who is

(a) in the case of a clinical trial respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and

7-6-01 (b) in any other case, a physician and a member in good standing of a professional medical association. (*chercheur qualifié*)

"**research ethics board**" means a body that is not affiliated with the sponsor, and

(a) the principal mandate of which is to approve the initiation of, and conduct periodic reviews of, biomedical research involving human subjects in order to ensure the protection of their rights, safety and well-being; and

(b) that has at least five members, that has a majority of members who are Canadian citizens or permanent residents under the *Immigration Act*, that is composed of both men and women and that includes at least

(i) two members whose primary experience and expertise are in a scientific discipline, who have broad experience in the methods and areas of research to be approved and one of whom is from a medical discipline or, if the clinical trial is in respect of a drug to be used for dental purposes only, is from a medical or dental discipline,

(ii) one member knowledgeable in ethics,

(iii) one member knowledgeable in Canadian laws relevant to the biomedical research to be approved,

(iv) one member whose primary experience and expertise are in a non-scientific discipline, and

(v) one member who is from the community or is a representative of an organization interested in the areas of research to be approved and who is not affiliated with the sponsor or the site where the clinical trial is to be conducted. (*comité d'éthique de la recherche*)

"**serious adverse drug reaction**" means an adverse drug reaction that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death. (*réaction indésirable grave à une drogue*)

"**serious unexpected adverse drug reaction** " means a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out in the investigator's brochure or on the label of the drug. (*réaction indésirable grave et imprévue à une drogue*)

"**sponsor**" means an individual, corporate body, institution or organization that conducts a clinical trial. (*promoteur*)

Application

C.05.002. (1) Subject to subsection (2), this Division applies to the sale or importation of drugs to be used for the purposes of clinical trials involving human subjects.

(2) Except for paragraph C.05.003(a), subsections C.05.006(2) and (3), paragraphs C.05.010(a) to (i), section C.05.011, subsections C.05.012(1) and (2), paragraphs C.05.012(3)(a) to (d) and (f) to (h), subsection C.05.012(4) and sections C.05.013, C.05.016 and C.05.017, this Division does not apply to the sale or importation of a drug for the purposes of a clinical trial authorized under subsection C.05.006(2).

Prohibition

C.05.003. Despite sections C.01.014, C.08.002 and C.08.003, no person shall sell or import a drug for the purposes of a clinical trial unless

(a) the person is authorized under this Division;

(b) the person complies with this Division and sections C.01.015, C.01.036, C.01.037 to C.01.040, C.01.040.2, C.01.064 to C.01.067, C.01.070, C.01.131, C.01.133 to C.01.136, and C.01.435; and

(c) if the drug is to be imported, the person has a representative in Canada who is responsible for the sale o the drug.

General

C.05.004. Despite these Regulations, a sponsor may submit an application under this Division to sell or import a drug for the purposes of a clinical trial that contains a substance the sale of which is prohibited by these Regulations, if the sponsor establishes, on the basis of scientific information, that the inclusion of the substance in the drug may result in a therapeutic benefit for a human being.

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Application for Authorization

C.05.005. An application by a sponsor for authorization to sell or import a drug for the purposes of a clinical trial under this Division shall be submitted to the Minister, signed and dated by the sponsor's senior medical or scientific officer in Canada and senior executive officer and shall contain the following information and documents:

(a) a copy of the protocol for the clinical trial;

(b) a copy of the statement, as it will be set out in each informed consent form, that states the risks and anticipated benefits arising to the health of clinical trial subjects as a result of their participation in the clinical trial;

(c) a clinical trial attestation, signed and dated by the sponsor's senior medical or scientific officer in Canada and senior executive officer, containing
  (i) the title of the protocol and the clinical trial number,
  (ii) the brand name, the chemical name or the code for the drug,
  (iii) the therapeutic and pharmacological classifications of the drug,
  (iv) the medicinal ingredients of the drug,
  (v) the non-medicinal ingredients of the drug,
  (vi) the dosage form of the drug,
  (vii) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the sponsor,
  (viii) if the drug is to be imported, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the sponsor's representative in Canada who is responsible for the sale of the drug,
  (ix) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the qualified investigator, if known at the time of submitting the application,

(x) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved the protocol referred to in paragraph (a) and approved an informed consent form containing the statement referred to in paragraph (b), if known at the time of submitting the application, and

(xi) a statement

(A) that the clinical trial will be conducted in accordance with good clinical practices and these Regulations, and

(B) that all information contained in, or referenced by, the application is complete and accurate and is not false or misleading;

(d) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of any research ethics board that has previously refused to approve the protocol referred to in paragraph (a), its reasons for doing so and the date on which the refusal was given, if known at the time of submitting the application;

(e) an investigator's brochure that contains the following information, namely,

(i) the physical, chemical and pharmaceutical properties of the drug,

(ii) the pharmacological aspects of the drug, including its metabolites in all animal species tested,

(iii) the pharmacokinetics of the drug and the drug metabolism, including the biological transformation of the drug in all animal species tested,

(iv) any toxicological effects in any animal species tested under a single dose study, a repeated dose study or a special study in respect of the drug,

(v) any results of carcinogenicity studies in any animal species tested in respect of the drug,

(vi) any results of clinical pharmacokinetic studies of the drug,

(vii) any information regarding drug safety, pharmacodynamics, efficacy and dose responses of the drug that were obtained from previous clinical trials in humans, and

(viii) if the drug is a radiopharmaceutical as defined in section C.03.201, information regarding directions for preparing the radiopharmaceutical, the radiation dosimetry in respect of the prepared radiopharmaceutical and a statement of the storage requirements for the prepared radiopharmaceutical;

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(f) if the drug contains a human-sourced excipient, including any used in the placebo,

(i) information that indicates the human-sourced excipient has been assigned a drug identification number under subsection C.01.014.2(1) or, in the case of a new drug, issued a notice of compliance under subsection C.08.004(1), as the case may be, or

(ii) in any other case, sufficient information to support the identify, purity, potency, stability and safety of the human-sourced excipient;

(g) if the drug has not been assigned a drug identification number under subsection C.01.014.2(1) or, in the case of a new drug, a notice of compliance has not been issued under subsection C.08.004(1), the chemistry and manufacturing information in respect of the drug, including its site of manufacture; and

(h) the proposed date for the commencement of the clinical trial at each clinical trial site, if known at the time of submitting the application.

Authorization

C.05.006. (1) Subject to subsection (3), a sponsor may sell or import a drug, other than a drug described in subsection (2), for the purposes of a clinical trial if

(a) the sponsor has submitted to the Minister an application in accordance with section C.05.005;

(b) the Minister does not, within 30 days after the date of receipt of the application, send to the sponsor a notice in respect of the drug indicating that the sponsor may not sell or import the drug for any of the following reasons:

(i) that the information and documents in respect of the application

(A) were not provided in accordance with these Regulations, or

(B) are insufficient to enable the Minister to assess the safety and risks of the drug or the clinical trial, or

(ii) that based on an assessment of the application, an assessment of any information submitted under section C.05.009 or a review of any other information, the Minister has reasonable grounds to believe that

(A) the use of the drug for the purposes of the clinical trial endangers the health of a clinical trial subject or other person,

(B) the clinical trial is contrary to the best interests of a clinical trial subject, or

(C) the objectives of the clinical trial will not be achieved;

(c) for each clinical trial site, the sponsor has obtained the approval of the research ethics board in respect of the protocol referred to in paragraph C.05.005(a) and in respect of an informed consent form that contains the statement referred to in paragraph C.05.005(b); and

(d) before the sale or importation of the drug at a clinical trial site, the sponsor submits to the Minister the information referred to in subparagraphs C.05.005(c)(ix) and (x) and paragraphs C.05.005(d) and (h), if it was not submitted in respect of that clinical trial site at the time of submitting the application.

(2) Subject to subsection (3), a sponsor may sell or import a drug for the purposes of a clinical trial in respect of

(a) a new drug that has been issued a notice of compliance under subsection C.08.004(1), if the clinical tria is in respect of a purpose or condition of use for which the notice of compliance was issued; or

(b) a drug, other than a new drug, that has been assigned a drug identification number under subsection C.01.014.2(1), if the clinical trial is in respect of a use or purpose for which the drug identification number was assigned.

(3) A sponsor may not sell or import a drug for the purposes of a clinical trial

(a) during the period of any suspension made under section C.05.016 or C.05.017; or

(b) after a cancellation made under section C.05.016 or C.05.017.

Notification

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C.05.007. If the sale or importation of a drug is authorized under this Division, the sponsor may make one or more of the following changes if the sponsor notifies the Minister in writing within 15 days after the date of the change:

(a) a change to the chemistry and manufacturing information that does not affect the quality or safety of the drug, other than a change for which an amendment is required by section C.05.008; and

(b) a change to the protocol that does not alter the risk to the health of a clinical trial subject, other than a change for which an amendment is required by section C.05.008.

Amendment

C.05.008. (1) Subject to subsections (4) and (5), when the sale or importation of a drug is authorized under this Division and the sponsor proposes to make an amendment referred to in subsection (2), the sponsor may sell or import the drug for the purposes of the clinical trial in accordance with the amended authorization, if the following conditions are met:

(a) the sponsor has submitted to the Minister an application for amendment in accordance with subsection (3);

(b) the Minister does not, within 30 days after the date of receipt of the application for amendment, send to the sponsor a notice in respect of the drug indicating that the sponsor may not sell or import the drug in accordance with the amendment for any of the following reasons, namely,

(i) that the information and documents in respect of the application for amendment

(A) were not provided in accordance with these Regulations, or

(B) are insufficient to enable the Minister to assess the safety and risks of the drug or the clinical trial, or

(ii) that based on an assessment of the application for amendment, an assessment of any information submitted under section C.05.009 or a review of any other information, the Minister has reasonable grounds to believe that

(A) the use of the drug for the purposes of the clinical trial endangers the health of a clinical trial subject or other person,

(B) the clinical trial is contrary to the best interests of a clinical trial subject, or

(C) the objectives of the clinical trial will not be achieved;

(c) before the sale or importation of the drug, the sponsor submits to the Minister

(i) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved any amended protocol submitted under paragraph (3)(a) or approved any amended statement submitted under paragraph (3)(c), and

(ii) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of any research ethics board that has previously refused to approve any amendment to the protocol, its reasons for doing so and the date on which the refusal was given;

(d) before the sale or importation of the drug, the sponsor maintains records concerning

(i) the information referred to in paragraph C.05.005(h), and

(ii) the information referred to in subparagraph C.05.005(c)(ix), if any of that information has changed since it was submitted;

(e) before the sale or importation of the drug in accordance with the amended authorization, the sponsor ceases to sell or import the drug in accordance with the existing authorization; and

(f) the sponsor conducts the clinical trial in accordance with the amended authorization.

(2) For the purposes of subsection (1), amendments are

(a) amendments to the protocol that affect the selection, monitoring or dismissal of a clinical trial subject;
(b) amendments to the protocol that affect the evaluation of the clinical efficacy of the drug;
(c) amendments to the protocol that alter the risk to the health of a clinical trial subject;
(d) amendments to the protocol that affect the safety evaluation of the drug;
(e) amendments to the protocol that extend the duration of the clinical trial; and
7-6-01 (f) amendments to the chemistry and manufacturing information that may affect the safety or quality of the drug.

(3) The application for amendment referred to in subsection (1) shall contain a reference to the application submitted under section C.05.005 and shall contain the following documents and information:

(a) if the application is in respect of an amendment referred to in any of paragraphs (2)(a) to (e), a copy of the amended protocol that indicates the amendment, a copy of the protocol submitted under paragraph C.05.005(a), and the rationale for the amendment;

(b) if the application is in respect of an amendment referred to in paragraph (2)(e), a copy of the amended investigator's brochure or an addendum to the investigator's brochure that indicates the new information, including supporting toxicological studies and clinical trial safety data;

(c) if the application is in respect of an amendment referred to in any of paragraphs (2)(a) to (f) and, as a result of that amendment, it is necessary to amend the statement referred to in paragraph C.05.005(b), a copy of the amended statement that indicates the new information; and

(d) if the application is in respect of an amendment referred to in paragraph (2)(f), a copy of the amended chemistry and manufacturing information that indicates the amendment, and the rationale for that amendment.

(4) If the sponsor is required to immediately make one or more of the amendments referred to in subsection (2) because the clinical trial or the use of the drug for the purposes of the clinical trial endangers the health of a clinical trial subject or other person, the sponsor may immediately make the amendment and shall provide the Minister with the information referred to in subsection (3) within 15 days after the date of the amendment.

(5) A sponsor may not sell or import a drug for the purposes of a clinical trial

(a) during the period of any suspension made under section C.05.016 or C.05.017; or

(b) after a cancellation made under section C.05.016 or C.05.017.

Additional Information and Samples

C.05.009. If the information and documents submitted in respect of an application under section C.05.005 o an application for amendment under section C.05.008 are insufficient to enable the Minister to determine whether any of the reasons referred to in paragraph C.05.006(1)(b) or C.05.008(1)(b) exist, the Minister may require the sponsor to submit, within two days after receipt of the request, samples of the drug or additional information relevant to the drug or the clinical trial that are necessary to make the determination.

Sponsor's Obligations

Good Clinical Practices

C.05.010. Every sponsor shall ensure that a clinical trial is conducted in accordance with good clinical practices and, without limiting the generality of the foregoing, shall ensure that

(a) the clinical trial is scientifically sound and clearly described in a protocol;

(b) the clinical trial is conducted, and the drug is used, in accordance with the protocol and this Division;

(c) systems and procedures that assure the quality of every aspect of the clinical trial are implemented;

(d) for each clinical trial site, the approval of a research ethics board is obtained before the clinical trial begins at the site;

(e) at each clinical trial site, there is no more than one qualified investigator;

(f) at each clinical trial site, medical care and medical decisions, in respect of the clinical trial, are under the supervision of the qualified investigator;

(g) each individual involved in the conduct of the clinical trial is qualified by education, training and experience to perform his or her respective tasks;

(h) written informed consent, given in accordance with the applicable laws governing consent, is obtained from every person before that person participates in the clinical trial but only after that person has been informed of

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(i) the risks and anticipated benefits to his or her health arising from participation in the clinical trial, and

(ii) all other aspects of the clinical trial that are necessary for that person to make the decision to participate in the clinical trial;

(i) the requirements respecting information and records set out in section C.05.012 are met; and

(j) the drug is manufactured, handled and stored in accordance with the applicable good manufacturing practices referred to in Divisions 2 to 4 except sections C.02.019, C.02.025 and C.02.026.

Labelling

C.05.011. Despite any other provision of these Regulations respecting labelling, the sponsor shall ensure tha the drug bears a label that sets out the following information in both official languages:

(a) a statement indicating that the drug is an investigational drug to be used only by a qualified investigator;

(b) the name, number or identifying mark of the drug;

(c) the expiration date of the drug;

(d) the recommended storage conditions for the drug;

(e) the lot number of the drug;

(f) the name and address of the sponsor;

(g) the protocol code or identification; and

(h) if the drug is a radiopharmaceutical as defined in section C.03.201, the information required by subparagraph C.03.202(1)(b)(vi).

Records

C.05.012. (1) The sponsor shall record, handle and store all information in respect of a clinical trial in a way that allows its complete and accurate reporting as well as its interpretation and verification.

(2) The sponsor shall maintain complete and accurate records to establish that the clinical trial is conducted in accordance with good clinical practices and these Regulations.

(3) The sponsor shall maintain complete and accurate records in respect of the use of a drug in a clinical trial, including

(a) a copy of all versions of the investigator's brochure for the drug;

(b) records respecting each change made to the investigator's brochure, including the rationale for each change and documentation that supports each change;

(c) records respecting all adverse events in respect of the drug that have occurred inside or outside Canada, including information that specifies the indication for use and the dosage form of the drug at the time of the adverse event;

(d) records respecting the enrolment of clinical trial subjects, including information sufficient to enable all clinical trial subjects to be identified and contacted in the event that the sale of the drug may endanger the health of the clinical trial subjects or other persons;

(e) records respecting the shipment, receipt, disposition, return and destruction of the drug;

(f) for each clinical trial site, an undertaking from the qualified investigator that is signed and dated by the qualified investigator prior to the commencement of his or her responsibilities in respect of the clinical trial, that states that

(i) the qualified investigator will conduct the clinical trial in accordance with good clinical practices, and

(ii) the qualified investigator will immediately, on discontinuance of the clinical trial by the sponsor, i its entirety or at a clinical trial site, inform both the clinical trial subjects and the research ethics board of the discontinuance, provide them with the reasons for the discontinuance and advise them in writing of any potential risks to the health of clinical trial subjects or other persons;

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(g) for each clinical trial site, a copy of the protocol, informed consent form and any amendment to the protocol or informed consent form that have been approved by the research ethics board for that clinical trial site; and

(h) for each clinical trial site, an attestation, signed and dated by the research ethics board for that clinical trial site, stating that it has reviewed and approved the protocol and informed consent form and that the board carries out its functions in a manner consistent with good clinical practices.

(4) The sponsor shall maintain all records referred to in this Division for a period of 25 years.

Submission of Information and Samples

C.05.013. (1) The Minister shall require a sponsor to submit, within two days after receipt of the request, information concerning the drug or the clinical trial, or samples of the drug, if the Minister has reasonable grounds to believe that

(a) the use of the drug for the purposes of the clinical trial endangers the health of a clinical trial subject or other person;

(b) the clinical trial is contrary to the best interests of a clinical trial subject;

(c) the objectives of the clinical trial will not be achieved;

(d) a qualified investigator is not respecting the undertaking referred to in paragraph C.05.012(3)(f); or

(e) information submitted in respect of the drug or the clinical trial is false or misleading.

(2) The Minister may require the sponsor to submit, within seven days after receipt of the request, any information or records kept under section C.05.012, or samples of the drug, in order to assess the safety of the drug or the health of clinical trial subjects or other persons.

Serious Unexpected Adverse Drug Reaction Reporting

C.05.014. (1) During the course of a clinical trial, the sponsor shall inform the Minister of any serious unexpected adverse drug reaction in respect of the drug that has occurred inside or outside Canada as follows:

(a) if it is neither fatal nor life threatening, within 15 days after becoming aware of the information; and

(b) if it is fatal or life threatening, within seven days after becoming aware of the information.

(2) The sponsor shall, within eight days after having informed the Minister under paragraph (1)(b), submit to the Minister a complete report in respect of that information that includes an assessment of the importance and implication of any findings made.

(3) Sections C.01.016 and C.01.017 do not apply to drugs used for the purposes of a clinical trial.

Discontinuance of a Clinical Trial

C.05.015. (1) If a clinical trial is discontinued by the sponsor in its entirety or at a clinical trial site, the sponsor shall

(a) inform the Minister no later than 15 days after the date of the discontinuance;

(b) provide the Minister with the reason for the discontinuance and its impact on the proposed or ongoing clinical trials in respect of the drug conducted in Canada by the sponsor;

(c) as soon as possible, inform all qualified investigators of the discontinuance and of the reasons for the discontinuance, and advise them in writing of any potential risks to the health of clinical trial subjects or other persons; and

(d) in respect of each discontinued clinical trial site, stop the sale or importation of the drug as of the date o the discontinuance and take all reasonable measures to ensure the recovery of all unused quantities of the drug that have been sold.

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(2) If the sponsor has discontinued the clinical trial in its entirety or at a clinical trial site, the sponsor may resume selling or importing the drug for the purposes of a clinical trial in its entirety or at a clinical trial site if, in respect of each clinical trial site where the sale or importation is to be resumed, the sponsor submits to the Minister the information referred to in subparagraphs C.05.005(c)(ix) and (x) and paragraphs C.05.005(d) and (h).

Suspension and Cancellation

C.05.016. (1) Subject to subsection (2), the Minister shall suspend the authorization to sell or import a drug for the purposes of a clinical trial, in its entirety or at a clinical trial site, if the Minister has reasonable grounds to believe that

(a) the sponsor has contravened these Regulations of any provisions of the Act relating to the drug;

(b) any information submitted in respect of the drug or clinical trial is false or misleading;

(c) the sponsor has failed to comply with good clinical practices; or

(d) the sponsor has failed to provide
  (i) information or samples of the drug as required under section C.05.009 or C.05.013, or
  (ii) information or a report under section C.05.014.

(2) Subject to section C.05.017, the Minister shall not suspend an authorization referred to in subsection (1) unless

(a) the Minister has sent to the sponsor a written notice of the intention to suspend the authorization that indicates whether the authorization is to be suspended in its entirety or at a clinical trial site and the reason for the intended suspension;

(b) the sponsor has not, within 30 days after receipt of the notice referred to in paragraph (a), provided the Minister with information or documents that demonstrate that the authorization should not be suspended on the grounds that

(i) the situation giving rise to the intended suspension did not exist, or

(ii) the situation giving rise to the intended suspension has been corrected; and

(c) the Minister has provided the sponsor with the opportunity to be heard in paragraph (b).

(3) The Minister shall suspend the authorization by sending to the sponsor a written notice of suspension of the authorization that indicates the effective date of the suspension, whether the authorization is suspended in its entirety or at a clinical trial site and the reason for the suspension.

(4) If the Minister has suspended an authorization, the Minister shall

(a) reinstate the authorization in its entirety or at a clinical trial site, as the case may be, if within 30 days after the effective date of the suspension the sponsor provides the Minister with information or documents that demonstrate that the situation giving rise to the suspension has been corrected; or

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(b) cancel the authorization in its entirety or at a clinical trial site, as the case may be, if within 30 days after the effective date of the suspension the sponsor has not provided the Minister with the information or documents referred to in paragraph (a).

C.05.017. (1) The Minister shall suspend an authorization to sell or import a drug for the purposes of a clinical trial, in its entirety or at a clinical trial site, before giving the sponsor an opportunity to be heard if the Minister has reasonable grounds to believe that it is necessary to do so to prevent injury to the health of a clinical trial subject or other person.

(2) The Minister shall suspend the authorization by sending to the sponsor a written notice of suspension of the authorization that indicates the effective date of the suspension, whether the authorization is suspended in its entirety or at a clinical trial site and the reason for the suspension.

(3) If the Minister has suspended an authorization, the Minister shall

(a) reinstate the authorization in its entirety or at a clinical trial site, as the case may be, if within 60 days after the effective date of the suspension the sponsor provides the Minister with information or documents that demonstrate that the situation giving rise to the suspension did not exist or that it has been corrected; or

(b) cancel the authorization in its entirety or at a clinical trial site, as the case may be, if within 60 days after the effective date of the suspension the sponsor has not provided the Minister with the information or documents referred to in paragraph (a).

Canadian Standard Drugs

Conjugated Estrogens
Conjugated Estrogens for Injection
Conjugated Estrogens Tablets
Digitoxin
Digitoxin Tablets
Digoxin
Digoxin Elixir
Digoxin Injection
Digoxin Tablets
Esterified Estrogens
Esterified Estrogens Tablets
Gelatin
Thyroid

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General

C.06.001. In this Division

(a) solubility and specific gravity shall be determined at 25°C,
1-12-77 (b) Revoked by P.C. 1977-3383 of December 1, 1977
(c) tests for identity, quantitative tests for arsenic, lead, copper, zinc, fluorine, and sulphur dioxide, and limit tests shall be made by acceptable methods, and
(d) determination of physical and chemical constants shall be carried out by acceptable methods.

Conjugated Estrogens

C.06.002. [S]. Conjugated estrogens shall be the drug conjugated estrogens described in The Pharmacopeia of the United States of America, XVIII (1970), except that

(a) the dilute assay preparation A, assay preparations A and B and equilin reagent described therein shall be prepared by official method DO-29, Conjugated Estrogens, October 15, 1981; and
23-4-82 (b) the identification test described therein shall be performed by official method DO-29, Conjugated Estrogens, October 15, 1981.

Conjugated Estrogens for Injection

10-11-76 **C.06.003. [S]. Conjugated estrogens for injection** shall be the drug conjugated estrogens for injection described in The Pharmacopeia of the United States of America, XVIII (1970), except that

(a) the dilute assay preparation A, assay preparations A and B and equilin reagent described therein shall be prepared by official method DO-29, Conjugated Estrogens, October 15, 1981; and
23-4-82 (b) the identification test described therein shall be performed by official method DO-29, Conjugated Estrogens, October 15, 1981.

Conjugated Estrogens Tablets

C.06.004. [S]. Conjugated estrogens tablets shall be the drug conjugated estrogens tablets described in The Pharmacopeia of the United States of America, XVIII (1970), except that

(a) the dilute assay preparation A, assay preparations A and B and equilin reagent described therein shall be prepared by official method DO-29, Conjugated Estrogens, October 15, 1981; and
23-4-82 (b) the identification test described therein shall be performed by official method DO-29, Conjugated Estrogens, October 15, 1981.

C.06.100. Revoked by P.C. 1980-1850 of July 10, 1980.

C.06.101. Revoked by P.C. 1980-1850 of July 10, 1980.

Digitoxin

23-6-71 **C.06.120. [S]. Digitoxin** shall be the drug digitoxin described in the Pharmacopeia of the United States of America.

Sections C.06.121 and C.06.122 are revoked by P.C. 1971-1258 of June 23, 1971.

Digitoxin Tablets

24-5-72 **C.06.121. [S].** Digitoxin tablets shall be the drug digitoxin tablets described in the Pharmacopeia of the United States of America.

Digoxin

C.06.130. [S]. Digoxin shall be the drug digoxin described in the Pharmacopeia of the United States of America.

Digoxin Elixir

C.06.131. [S]. Digoxin Elixir shall be the drug digoxin elixir described in the Pharmacopeia of the United State of America.

Digoxin Injection

23-6-71

C.06.132. [S]. Digoxin injection shall be the drug digoxin injection described in the Pharmacopeia of the United States of America.

Digoxin Tablets

C.06.133. [S]. Digoxintablets shall be the drug digoxin tablets described in the Pharmacopeia of the United States of America.

Sections C.06.140, C.06.141, C.06.142, C.06.150, C.06.151, C.06.153, C.06.154, C.06.155, C.06.156 are revoked by P.C. 1980-1850 of July 10, 1980.

C.06.157. Revoked by P.C. 1980-1850 of July 10, 1980.

C.06.158. Revoked by P.C. 1980-1850 of July 10, 1980.

C.06.159. Revoked by P.C. 1980-1850 of July 10, 1980.

C.06.160. Revoked by P.C. 1980-1850 of July 10, 1980.

Esterified Estrogens

9-11-71 | **C.06.161. [S]. Esterified estrogens** shall be the drug esterified estrogens described in the Pharmacopeia of the United States of America.

Esterified Estrogens Tablets

23-6-71 | **C.06.162. [S]. Esterified estrogens tablets** shall be the drug esterified estrogens tablets described in the Pharmacopeia of the United States of America.

*(R) Minor correction

Gelatin

1-12-77 **C.06.170.** Gelatin shall be the drug gelatin described in the Pharmacopeia of the United States or the British Pharmacopeia.

C.06.180. Revoked by P.C. 1980-1850 of July 10, 1980.

C.06.181. Revoked by P.C. 1980-1850 of July 10, 1980.

Sections C.06.182, C.06.183, C.06.230, C.06.231, C.06.232, C.06.233, C.06.240, C.06.241, C.06.242 are revoked by P.C. 1980-1850 of July 10, 1980.

C.06.250. **Thyroid** shall be the cleaned, dried, powdered thyroid glands of domestic animals used for food, and shall contain not less than 0.17 per cent, and not more than 0.23 per cent iodine and no added iodine in either inorganic or organic form, and

(a) its characters are

Description,--

(i) General--thyroid occurs as a cream-coloured, amorphous powder; the odour and taste are faint and meat-like, and

(ii) Microscopical,--when suitably mounted and examined under the microscope, thyroid shows the following: numerous smooth to striated hyaline fragments of colloids, of angular to irregular shape, that are colourless to pale yellow in water mounts, brown in Mallory's stain and pink in solution of casin, some of these fragments containing granules, minute vacuoles, crystalloidal bodies and cells; numerous irregular fragments of folicular epithelium staining brown with Mallory's stain, the individual cells more or less polygonal to rounded-angular or irregularly cuboidal, often with prominent nuclei staining dark blue, their cytoplasm purplish with Delafield's solution of haematoxylin; slender glistening segments of capillaries of closely undulate outline; numerous slender segments of neuraxons; numerous aggregates of particles of intercellular substance and slender, mostly straight connective tissue fibres staining blue to greenish blue with a mixture of Mallory's stain and solution of phosphotungstic acid, the bundles of fibres often appearing reddish in Mallory's stain few glistening fragments of blood vessels with serrated or crenated ends as viewed in water mounts, and

(b) the test for its purity are

(i) Inorganic iodine--add to 1 gram of thyroid 10 millilitres of a saturated solution of zinc sulphate in water, shake, allow to stand 5 minutes, and filter through a fritted glass filter; add to 5 millilitres of the filtrate 0.5 millilitre of mucilage of starch and 4 drops each of a 10 per cent w/v solution of sodium nitrite in water and dilute sulphuric acid, shaking after each addition: no blue colour is produced, and

(ii) Moisture,--thyroid loses not more than 6 per cent moisture.

C.06.251. Thyroid shall be

23-4-82 | (a) assayed by official method DO-26, Thyroid, October 15, 1981; and
(b) stored in a cool place and in a tightly-closed container.

Sections C.06.252, C.06.260, C.06.261, C.06.262, C.06.263, C.06.264, C.06.270, C.06.271, C.06.272, C.06.273, C.06.274, C.06.275, C.06.276, C.06.277, C.06.278, C.06.279, C.06.280 are revoked by P.C. 1980-1850 of July 10, 1980.

ANNEX TO DIVISION 6

Revoked by P.C. 1977-3383 of December 1, 1977

Sale of Drugs for the Purposes of Implementing the General Council Decision

Interpretation

C.07.001. The definitions in this section apply in this Division.

"Commissioner of Patents" means the Commissioner of Patents appointed under subsection 4(1) of the *Patent Act*. (*commissaire aux brevets*)
"General Council Decision" has the meaning assigned by subsection 30(6) of the Act. (*décision du Conseil général*)

Application

C.07.002. This Division applies to the sale of drugs for the purposes of implementing the General Council Decision.

Application for Authorization

C.07.003. An application by a manufacturer for authorization to sell a drug under this Division shall be submitted to the Minister and shall contain the following information and documents:

(a) a statement that the manufacturer intends to file an application with the Commissioner of Patents under section 21.04 of the *Patent Act*;
(b) in respect of a new drug, the submission number and date of filing of the new drug submission or abbreviated new drug submission filed under section C.08.002 or C.08.002.1, respectively, and of any supplement filed under section C.08.003 in respect of the drug;
(c) in respect of a drug that is not a new drug,
  (i) the application number and date of filing of the application that has been filed under section C.01.014.1 in respect of the drug, or
  (ii) the drug identification number, if one has been assigned in respect of the drug pursuant to section C.01.014.2; 10-5-05
(d) for a drug in a solid dosage form, the manner in which the drug is marked in accordance with paragraph C.07.008(a) and evidence that such manner does not alter the safety and efficacy of the drug;
(e) for a drug in a dosage form that is not solid, the manner in which the immediate container is marked in accordance with paragraph C.07.008(a); and
(f) a sample of the label for the drug that includes the information required by paragraph C.07.008(c).

Authorization

C.07.004. The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.04(3)(b) of the *Patent Act* that the manufacturer's drug meets the requirements of the Act and these Regulations if

(a) the manufacturer has submitted to the Minister an application in accordance with section C.07.003 and a copy of the application filed by the manufacturer with the Commissioner of Patents under section 21.04 of the *Patent Act*;
(b) in respect of a new drug, an examination of the new drug submission or abbreviated new drug submission or supplement to either submission by the Minister demonstrates that the submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1;
(c) in respect of a drug that is not a new drug, a drug identification number has been assigned pursuant to section C.01.014.2; and
(d) the Minister is satisfied that the manufacturer and the drug comply with the Act and these Regulations.

C.07.005. Despite sections C.01.014, C.08.002 and C.08.003, a manufacturer may sell a drug under this Division if

(a) the Minister has notified the Commissioner of Patents for the purposes of paragraph 21.04(3)(b) of the *Patent Act* that the drug meets the requirements of the Act and these Regulations; and
(b) the manufacturer has received authorization under section 21.04 of the *Patent Act*.

C.07.006. Sections C.01.005 and C.01.014.1 to C.01.014.4 do not apply to new drugs sold under this Division.

Notice to Commissioner of Patents

C.07.007. The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.13(b) of the *Patent Act* in the event that the Minister is of the opinion that the manufacturer's drug authorized to be sold under this Division has ceased to meet the requirements of the Act and these Regulations.

Marking and Labelling

C.07.008. No person shall sell a drug under this Division unless

(a) the drug itself permanently bears the mark "XCL", in the case of a drug in a solid dosage form, or the immediate container permanently bears the mark "XCL", in the case of a drug in a dosage form that is not solid;
(b) the colour of the drug itself is significantly different from the colour of the version of the drug sold in Canada, in the case of a drug in a solid dosage form; and
(c) the label of the drug permanently bears the mark "XCL", followed by the export tracking number assigned by the Minister under section C.07.009 and the words "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA." or "POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA.".

10-5-05

C.07.009. The Minister shall assign an export tracking number to each drug in respect of which the Minister has notified the Commissioner of Patents under section C.07.004.

Records

C.07.010. The manufacturer shall, with respect to a drug authorized to be sold under this Division,

(a) establish and maintain records, in a manner that enables an audit to be made, respecting the information described in section C.08.007; and
(b) provide to the Minister the reports referred to in section C.08.008.

Notice to Minister

C.07.011. The manufacturer shall notify the Minister in writing not less than 15 days before commencing the manufacture of the first lot of a drug authorized to be sold under this Division and not less than 15 days before the exportation of each subsequent lot of the drug.

New Drugs

4-4-95 **C.08.001.** For the purposes of the Act and this Division, "new drug" means

(a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use a a drug;

(b) a drug that is a combination of two or more drugs, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that combination and proportion for use as a drug; or

(c) a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, route of administration, or duration of action and that has not been sold for that use or condition of use in Canada, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that use or condition of use of that drug.

C.08.001.1. For the purposes of this Division,

"**Canadian reference product**" means

(a) a drug in respect of which a notice of compliance is issued pursuant to section C.08.004 and which is marketed in Canada by the innovator of the drug,

(b) a drug, acceptable to the Minister, that can be used for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics, where a drug in respect of which a notice of compliance has been issued pursuant to section C.08.004 cannot be used for that purpose because it is no longer marketed in Canada, or

16-8-95 (c) a drug, acceptable to the Minister, that can be used for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics, in comparison to a drug referred to in paragraph (a); (produit de référence canadien)

"**pharmaceutical equivalent**" means a new drug that, in comparison with another drug, contains identical amounts of the identical medicinal ingredients, in comparable dosage forms, but that does not necessarily contain the same non-medicinal ingredients; (équivalent pharmaceutique)

"**specifications**" means a detailed description of a new drug and of its ingredients and includes

(a) a statement of all properties and qualities of the ingredients that are relevant to the manufacture and use of the new drug, including the identity, potency and purity of the ingredients,

(b) a detailed description of the methods used for testing and examining the ingredients, and

(c) a statement of the tolerances associated with the properties and qualities of the ingredients. (spécifications)

C.08.002. (1) No person shall sell or advertise a new drug unless

(a) the manufacturer of the new drug has filed with the Minister a new drug submission or an abbreviated new drug submission relating to the new drug that is satisfactory to the Minister;

16-8-95 (b) the Minister has issued, pursuant to section C.08.004, a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission;

(c) the notice of compliance in respect of the submission has not been suspended pursuant to section C.08.006; and

(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any labels, including package inserts, product brochures and file cards, intended for use in connection with that new drug, and a statement setting out the proposed date on which those labels will first be used.

16-8-95 (2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

20-4-93 (a) a description of the new drug and a statement of its proper name or its common name if there is no proper name;

(b) a statement of the brand name of the new drug or the identifying name or code proposed for the new drug;

(c) a list of the ingredients of the new drug, stated quantitatively, and the specifications for each of those ingredients;

16-8-95 (d) a description of the plant and equipment to be used in the manufacture, preparation and packaging of the new drug;

(e) details of the method of manufacture and the controls to be used in the manufacture, preparation and packaging of the new drug;

(f) details of the tests to be applied to control the potency, purity, stability and safety of the new drug;
(g) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;
(h) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended;
20-4-93 (i) a statement of the names and qualifications of all the investigators to whom the new drug has been sold;
(j) a draft of every label to be used in conjunction with the new drug;
(k) a statement of all the representations to be made for the promotion of the new drug respecting
(i) the recommended route of administration of the new drug,
(ii) the proposed dosage of the new drug,
(iii) the claims to be made for the new drug, and
(iv) the contra-indications and side effects of the new drug;
(l) a description of the dosage form in which it is proposed that the new drug be sold;
16-8-95 (m) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production; and
(n) for a drug intended for administration to food-producing animals, the withdrawal period of the new drug.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of a new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

16-8-95 (a) the names and addresses of the manufacturers of each of the ingredients of the new drug and the name and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;
(b) samples of the ingredients of the new drug;
(c) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and
(d) any additional information or material respecting the safety and effectiveness of the new drug.

C.08.002.1. (1) A manufacturer of a new drug may file an abbreviated new drug submission for the new drug where, in comparison with a Canadian reference product,

(a) the new drug is the pharmaceutical equivalent of the Canadian reference product;
(b) the new drug is bioequivalent with the Canadian reference product, based on the pharmaceutical and, where the Minister considers it necessary, bioavailability characteristics;
(c) the route of administration of the new drug is the same as that of the Canadian reference product; and
(d) the conditions of use for the new drug fall within the conditions of use for the Canadian reference product.

(2) An abbreviated new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(a) the information and material described in paragraphs C.08.002(2)(a) to (f) and (j) to (l);
(b) information identifying the Canadian reference product used in any comparative studies conducted in connection with the submission;
16-8-95 (c) evidence from the comparative studies conducted in connection with the submission that the new drug is
(i) the pharmaceutical equivalent of the Canadian reference product, and
(ii) where the minister considers it necessary on the basis of the pharmaceutical and, where applicable, bioavailability characteristics of the new drug, bioequivalent with the Canadian reference product as demonstrated using bioavailability studies, pharmacodynamic studies or clinical studies;
(d) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production; and
(e) for a drug intended for administration to food-producing animals, sufficient information to confirm that the withdrawal period is identical to that of the Canadian reference product.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of an abbreviated new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

(a) the names and addresses of the manufacturers of each of the ingredients of the new drug and the name and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;
(b) samples of the ingredients of the new drug;
(c) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and
(d) any additional information or material respecting the safety and effectiveness of the new drug.

C.08.003. (1) Notwithstanding section C.08.002, no person shall sell a new drug in respect of which a notic of compliance has been issued to the manufacturer of that new drug and has not been suspended pursuant to section C.08.006, if any of the matters specified in subsection (2) are significantly different from the information or material contained in the new drug submission or abbreviated new drug submission, unless

(a) the manufacturer of the new drug has filed with the Minister
  (i) a supplement to that new drug submission, or
  (ii) a supplement to that abbreviated new drug submission;
(b) the Minister has issued a notice of compliance to the manufacturer of the new drug in respect of the supplement;
(c) the notice of compliance in respect of the supplement has not been suspended pursuant to section C.08.006; and
(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any label, including any package insert, product brochure and file card, intended for use in connection with the new drug, where a change with respect to any of the matters specified in subsection (2) is made that would require a change to the label.

(2) The matters specified for the purposes of subsection (1), in relation to the new drug, are the following:

(a) the description of the new drug;
(b) the brand name of the new drug or the identifying name or code proposed for the new drug;
16-8-95 (c) the specifications of the ingredients of the new drug;
(d) the plant and equipment used in manufacturing, preparation and packaging the new drug;
(e) the method of manufacture and the controls used in manufacturing, preparation and packaging the new drug;
(f) the tests applied to control the potency, purity, stability and safety of the new drug;
(g) the labels used in connection with the new drug;
(h) the representations made with regard to the new drug respecting
  (i) the recommended route of administration of the new drug,
  (ii) the dosage of the new drug,
  (iii) the claims made for the new drug,
  (iv) the contra-indications and side effects of the new drug, and
  (v) the withdrawal period of the new drug; and
(i) the dosage form in which it is proposed that the new drug be sold.

(3) A supplement to a new drug submission or to an abbreviated new drug submission, with respect to the matters that are significantly different from those contained in the submission, shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug in relation to those matters.

7-6-01 **C.08.003.1.** The Minister may examine any information or material filed with the Minister by any person pursuant to Division 5 or section C.08.002, C.08.002.1, C.08.003, C.08.005 or C.08.005.1 to establish the safety and effectiveness of the new drug for which the submission or supplement has been filed.

C.08.004. (1) Subject to section C.08.004.1, the Minister shall, after completing an examination of a new drug submission or abbreviated new drug submission or a supplement to either submission,

(a) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or
16-8-95 (b) if that submission or supplement does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does no so comply.

(2) Where a new drug submission or abbreviated new drug submission or a supplement to either submission does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, the manufacturer who filed the submission or supplement may amend the submission or supplement by filing additional information or material.

(3) Subject to section C.08.004.1, the Minister shall, after completing an examination of any additional information or material filed in respect of a new drug submission or an abbreviated new drug submission or a supplement to either submission,

(a) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or
(b) if that submission or supplement does not comply with the requirements of section C.08.002, C.08.002. or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

(4) A notice of compliance issued in respect of a new drug on the basis of information and material contained in a submission filed pursuant to section C.08.002.1 shall state the name of the Canadian reference product referred to in the submission and shall constitute a declaration of equivalence for that new drug.

16-8-95 **C.08.004.1.*** (1) Where a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to an abbreviated new drug submission for the purpose of establishing the safety and effectiveness of the new drug for which the submission or supplement is filed, and the Minister examines any information of material filed with the Minister, in a new drug submission, by the innovator of a drug that contains a chemical or biological substance not previously approved for sale in Canada as a drug, and the Minister, in support of the manufacturer's submission or supplement, relies on data contained in the information or material filed by the innovator, the Minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the date of issuance to the innovator of the notice of compliance or approval to market that drug, as the case may be, issued on the basis of the information or material filed by the innovator for that drug.

(2) Subsection (1) does not apply where the manufacturer of a new drug for which a notice of compliance was issued pursuant to section C.08.004 gives written permission to another manufacturer to rely on the test or other data filed in respect of that new drug.

(3) Subsection (1) does not apply where the data relied upon by the Minister was contained in information or material filed by the innovator before January 1, 1994.

5-10-06 **C.08.004.1.**** (1) The following definitions apply in this section.

"innovative drug" means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (*drogue innovante*)

"pediatric populations" means the following groups: premature babies born before the 37 th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age. (*population pédiatrique*)

(2) This section applies to the implementation of Article 1711 of the North American Free Trade Agreement, as defined in the definition "Agreement" in subsection 2(1) of the *North American Free Trade Agreement Implementation Act*, and of paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the World Trade Organization Agreement, as defined in the definition "Agreement" in subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.

(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,

(a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and
(b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.

* *Applies to a drug in respect of which a notice of compliance was issued before June 17, 2006.*

** *Applies to a drug in respect of which a notice of compliance was issued on June 17, 2006 or after.*

(4) The period specified in paragraph (3)(b) is lengthened to eight years and six months if

(a) the innovator provides the Minister with the description and results of clinical trials relating to the use of the innovative drug in relevant pediatric populations in its first new drug submission for the innovative drug or in any supplement to that submission that is filed within five years after the issuance of the first notice of compliance for that innovative drug; and

(b) before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug, the Minister determines that the clinical trials were designed and conducted for the purpose of increasing knowledge of the use of the innovative drug in those pediatric populations and this knowledge would thereby provide a health benefit to members of those populations.

(5) Subsection (3) does not apply if the innovative drug is not being marketed in Canada.

(6) Paragraph (3)(a) does not apply to a subsequent manufacturer if the innovator consents to the filing of a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission by the subsequent manufacturer before the end of the period of six years specified in that paragraph.

(7) Paragraph (3)(a) does not apply to a subsequent manufacturer if the manufacturer files an application for authorization to sell its new drug under section C.07.003.

(8) Paragraph (3)(b) does not apply to a subsequent manufacturer if the innovator consents to the issuance of a notice of compliance to the subsequent manufacturer before the end of the period of eight years specified in that paragraph or of eight years and six months specified in subsection (4).

(9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4).

7-6-01 **C.08.005.** (1) Subject to subsection (1.1) and notwithstanding sections C.08.002 and C.08.003, a manufacturer of a new drug may sell it to a qualified investigator to be used solely for the purpose of clinical testing to obtain evidence with respect to the safety, dosage and effectiveness of that new drug, when the following conditions are met:

16-8-95 (a) before the sale, the manufacturer has filed with the Minister, in compliance with section C.08.005.1, a preclinical submission containing information and material respecting

20-4-93 (i) the brand name of the new drug or the identifying name or code proposed for the new drug,

(ii) the chemical structure or other specific identification of the composition of the new drug,

(iii) the source of the new drug,

(iv) a detailed protocol of the clinical testing,

(v) the results of investigations made to support the clinical use of the new drug,

(vi) the contra-indications and precautions known in respect of the new drug and the suggested treatment of overdosage of the new drug,

(vii) all ingredients of the new drug, stated quantitatively,

(viii) the methods, equipment, plant and controls used in the manufacture, processing and packaging o the new drug,

(ix) the tests applied to control the potency, purity and safety of the new drug, and

(x) the names and qualifications of all investigators to whom the drug is to be sold and the names of all institutions in which the clinical testing is to be carried out;

14-8-87 (b) the Director has not, within 60 days after the date of receipt of the preclinical submission, sent by registered mail to the manufacturer a notice in respect of that new drug indicating that the preclinical submission is not satisfactory;

(c) all inner labels and outer labels used in conjunction with the sale of the new drug to qualified investigators carry the statements

(i) "Investigational Drug" or "Drogue de recherche", and

(ii) "To Be Used By Qualified Investigators Only" or "Réservée uniquement à l'usage de chercheurs compétents";

(d) before the sale, the manufacturer ascertains that every qualified investigator to whom the new drug is to be sold

(i) has the facilities for the clinical testing to be conducted by the investigator, and

(ii) has received the information and material referred to in subparagraphs (a)(i) to (vi); and

(e) every qualified investigator to whom the new drug is to be sold has agreed in writing with the manufacturer that the investigator will
  (i) not use the new drug or permit it to be used other than for clinical testing,
  (ii) not permit the new drug to be used by any person other than the investigator except under the investigator's direction,
  (iii) report immediately to that manufacturer and, if so required by the Director, report to the Director all serious adverse reactions encountered during the clinical testing, and
  (iv) account to the manufacturer for all quantities of the new drug received, where so requested by the manufacturer.

7-6-01 (1.1) This section applied only in respect of a new drug for veterinary use.

(2) Notwithstanding subsection (1), no manufacturer shall sell a new drug to a qualified investigator unless that manufacturer has, in respect of all previous sales of that new drug to any qualified investigator,

(a) kept accurate records of the distribution of that new drug and of the results of the clinical testing and has made those records available to the Director for inspection on the request of the Director; and
(b) immediately reported to the Director all information he has obtained with respect to serious adverse reactions.

(3) The Minister may notify the manufacturer of a new drug that sales of that new drug to qualified investigators are prohibited if, in the opinion of the Minister, it is in the interest of public health to do so.

(4) Notwithstanding subsection (1), no manufacturer shall sell a new drug to a qualified investigator if the Minister has notified the manufacturer of that drug that such sales are prohibited.

14-8-87 (5) Paragraph (1)(c) does not apply to a radiopharmaceutical as defined in section C.03.201, or to a component or kit as defined in section C.03.205.

7-6-01 **C.08.005.1** (1) Every manufacturer who files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission, a supplement to an abbreviated new drug submission or a submissio for the clinical testing of a new drug for veterinary use shall, in addition to any information and material that is required under section C.08.002, C.08.003 and C.08.005, include in the submission or supplement

(a) a copy of all clinical case reports respecting any subject of a study included in the submission or supplement if that subject has died, suffered a serious adverse reaction or an unexpected adverse reaction, or the study, insofar as it relates to this subject, has not been completed;
(b) a sectional report in respect of each human, animal and in vitro study included in the submission or supplement;
(c) a comprehensive summary of each human, animal and in vitro study referred to or included in the submission or supplement; and
(d) a submission certificate in respect of all information and material contained in the submission or supplement and any additional information or material filed to amend the submission or supplement.

(2) A sectional report referred to in paragraph (1)(b) shall include
(a) a summary of each study included in the submission or supplement;
(b) a summary of any additional information or material filed to amend the submission or supplement; and
(c) where raw data is available to the manufacturer in respect of a study,
  (i) a summary of the data,
  (ii) a cross-referencing of the data to the relevant portions of the sectional report,
  (iii) a description of the conditions under which the experiments from which the data were obtained were conducted,
17-9-92 (iv) the details of the data treatment process, and
  (v) the results and conclusions of the study.

(3) The comprehensive summary referred to in paragraph (1)(c) shall include a summary of the methods used, results obtained and conclusions arrived at in respect of all studies referred to or included in the submission or supplement and shall be cross-referenced to the relevant portions of the section reports.

(4) The submission certificate referred to in paragraph (1)(d) shall
(a) certify that all information and material included in the submission or supplement and any additional information or material filed to amend the submission or supplement are accurate and complete, and that the sectional reports and the comprehensive summary correctly represent the information and material referred to or included in the submission or supplement; and
(b) be signed and dated by
  (i) the senior executive officer in Canada of the manufacturer filing the submission or supplement, and
  (ii) the senior medical or scientific officer of the manufacturer.

(5) No person shall sign a submission certificate if a sectional report, comprehensive summary or any information or material included in the submission or supplement, or any additional information and material filed to amend the submission or supplement,

(a) is false or misleading; or

(b) contains omissions that may affect its accuracy and completeness.

7-6-01 (6) Every manufacturer who has filed a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission, a supplement to an abbreviated new drug submission or a submission for the clinical testing of a new drug for veterinary use, and has any relating clinical case reports or raw data that were not included therein, shall keep those reports or data and shall, within 30 days after receiving a written request from the Minister, submit them to the Minister.

7-6-01 **C.08.006.** (1) For the purposes of this section, evidence or new information obtained by the Minister includes any information or material filed by any person pursuant to Division 5 or section C.08.002, C.08.002.1, C.08.003, C.08.005 or C.08.005.1.

16-8-95 (2) The Minister may, by notice to a manufacturer, suspend, for a definite or indefinite period, a notice of compliance issued to that manufacturer in respect of a new drug submission or an abbreviated new drug submission or a supplement to either submission, if the Minister considers

(a) that the drug is not safe for the use represented in the submission or supplement, as shown by evidence obtained from

(i) clinical or other experience not reported in the submission or supplement or not available to the Minister at the time the notice of compliance was issued, or

(ii) tests by new methods or tests by methods not reasonably applicable at the time the notice of compliance was issued;

(b) that upon the basis of new information obtained after the issuance of the notice of compliance, there is lack of substantial evidence that the drug will have the effect it is represented to have under the conditions of use prescribed, recommended or proposed by the manufacturer;

16-8-95 (c) that the submission or supplement contained an untrue statement of material fact;

(d) that the manufacturer has failed to establish a system for maintaining required records or has repeatedly or deliberately failed to maintain such records;

10-10-63 (e) that, on the basis of new information obtained after the issuance of the notice of compliance, the methods, equipment, plant and controls used in the manufacturing, processing and packaging of the drug are inadequate to assure and preserve the identity, strength, quality or purity of the new drug; or

(f) that, on the basis of new information obtained after the issuance of the notice of compliance, the labelling of the drug is false or misleading or incomplete in any particular and that this defect was not corrected by the manufacturer upon receipt of a written notice from the Director specifying the respect in which the labelling is false or misleading or incomplete.

16-8-95 **C.08.007.** Where a manufacturer has received a notice of compliance issued in respect of a new drug submission or abbreviated new drug submission or a supplement to either submission, the manufacturer shall establish and maintain records, in a manner that enables an audit to be made, respecting

(a) animal or clinical experience, studies, investigations and tests conducted by the manufacturer or reported to him by any person concerning that new drug;

(b) reports from the scientific literature or the bibliography therefrom that are available to him concerning that new drug;

10-10-63 (c) experience, investigations, studies and tests involving the chemical or physical properties or any other properties of that new drug;

(d) any substitution of another substance for that new drug or any mixing of another substance with that new drug;

(e) any error in the labelling of that new drug or in the use of the labels designed for that new drug;

(f) any bacteriological or any significant chemical or physical or other change or deterioration in any lot of that new drug;

16-8-95 (g) any failure of one or more distributed lots of the new drug to meet the specifications established for that new drug in the submission or supplement; and

7-11-95 (h) any unusual failure in efficacy of that new drug.

C.08.008. No manufacturer shall sell a new drug unless the manufacturer has, with respect to all the manufacturer's previous sales of that new drug, furnished to the Minister

16-8-95 (a) on request, reports of all records respecting the information described in paragraphs C.08.007(a) to (c);

(b) immediately on receipt by the manufacturer, reports of all records respecting the information described in paragraphs C.08.007(d) to (f); and

7-11-95 (c) within 15 days after the receipt by the manufacturer of information referred to in paragraphs C.08.007(g) and (h), a report on the information received.

C.08.009. (1) Where the Minister has decided

7-6-01 (a) to notify the manufacturer of a new drug for veterinary use that the sale of that drug to qualified investigators is prohibitied, or

16-8-95 (b) to suspend a notice of compliance issued in respect of a new drug submission or an abbreviated new drug submission or a supplement to either submission,

the manufacturer, if dissatisfied with that decision, may require the Minister to provide him with the reasons for the decision.

(2) Where the manufacturer has received the reasons for a decision of the Minister pursuant to subsection (1), he may require the Minister to refer that decision to a New Drug Committee and thereupon shall provide the Minister with a statement of the reasons for his dissatisfaction and any information and material upon which he relies in support of those reasons.

(3) Where the Minister has been required to refer a decision to a New Drug Committee pursuant to subsection (2), he shall appoint a member of the New Drug Committee, the dissatisfied manufacturer shall appoint a member of the New Drug Committee and the two members so appointed shall appoint a third member of the New Drug Committee who shall be chairman, or, if they are unable to do so within a reasonable time, the Minister shall appoint a third member of the New Drug Committee who shall be chairman.

10-10-63 (4) Any person who is in the full-time employment of the Department or in the full-time employment of the dissatisfied manufacturer shall not be appointed a member of a New Drug Committee.

16-8-95 (4.1) A member of a New Drug Committee shall, on appointment, sign an undertaking not to disclose or use any information, material, data, evidence or representations considered pursuant to subsection (6).

(5) The Minister shall pay the reasonable fees and costs incurred by the member of the New Drug Committee appointed by the Minister, and the dissatisfied manufacturer shall pay the reasonable fees and costs incurred by the member appointed by the dissatisfied manufacturer, and the Minister and the dissatisfied manufacturer shall each pay half of the reasonable fees and costs incurred by the chairman.

10-10-63 (6) The New Drug Committee formed pursuant to subsection (3) shall consider the reasons for the decision of the Minister, the reasons for the dissatisfaction of the dissatisfied manufacturer and any information or material in support of the reasons of the Minister or the dissatisfied manufacturer and may consider other evidence, material, information or representations.

(7) The New Drug Committee formed pursuant to subsection (3) shall report its findings and recommendations to the Minister.

16-8-95 (7.1) No member of a New Drug Committee shall disclose or use any information, material, data, evidence or representations considered pursuant to subsection (6).

(8) Where the Minister has received the findings and recommendations of a New Drug Committee he may reconsider the decision to which those findings and recommendations relate.

Sale of New Drug for Emergency Treatment

C.08.010. (1) The Director may issue a letter of authorization authorizing the sale of a quantity of a new drug for human or veterinary use to a practitioner named in the letter of authorization for use in the emergency treatment of a patient under the care of that practitioner, if

(a) the practitioner has supplied to the Director information concerning

10-11-66 (i) the medical emergency for which the drug is required,

(ii) the data in the possession of the practitioner with respect to the use, safety and efficacy of that drug,

(iii) the names of all institutions in which the drug is to be used, and

(iv) such other data as the Director may require; and

(b) the practitioner has agreed to
(i) report to the manufacturer of the new drug and to the Director on the results of the use of the drug in the medical emergency, including information respecting any adverse reactions encountered, and
(ii) account to the Director on request for all quantities of the drug received by him.

10-11-66

(2) The Director shall, in any letter of authorization issued pursuant to subsection (1) state
(a) the name of the practitioner to whom the new drug may be sold;
(b) the medical emergency in respect of which the new drug may be sold; and
(c) the quantity of the new drug that may be sold to that practitioner for that emergency.

C.08.011. (1) Notwithstanding section C.08.002, a manufacturer may sell to a practitioner named in a lette of authorization issued pursuant to section C.08.010, a quantity of the new drug named in that letter that does not exceed the quantity specified in the letter.

10-11-66

(2) A sale of a new drug made in accordance with subsection (1) is exempt from the provisions of the Act and these Regulations.

Sale of Medicated Feeds

C.08.012. (1) Notwithstanding anything in this Division, a person may sell, pursuant to a written prescription of a veterinary practitioner, a medicated feed if

(a) as regards the drug or drugs used as the medicating ingredient of the medicated feed,
20-2-92 (i) the Director has assigned a drug identification number pursuant to section C.01.014.2, or
(ii) the sale is permitted by section C.08.005, C.08.011 or C.08.013;
(b) the medicated feed is for the treatment of animals under the direct care of the veterinary practitioner who signed the prescription;
(c) the medicated feed is for therapeutic purposes only; and
(d) the written prescription contains the following information:
(i) the name and address of the person named on the prescription as the person for whom the medicated feed is to be mixed,
12-9-80 (ii) the species, production type and age or weight of the animals to be treated with the medicated feed,
(iii) the type and amount of medicated feed to be mixed,
20-4-93 (iv) the proper name, or the common name if there is no proper name, of the drug or each of the drugs as the case may be, to be used as medicating ingredients in the preparation of the medicated feed, and the dosage levels of those medicating ingredients,
(v) any special mixing instructions, and
(vi) labelling instructions including
(A) feeding instructions,
(B) a warning statement respecting the withdrawal period to be observed following the use of the medicated feed, and
(C) where applicable, cautions with respect to animal health or to the handling or storage of the medicated feed.

(2) For the purpose of this section, "medicated feed" has the same meaning as in the Feeds Regulations.

EXPERIMENTAL STUDIES

Conditions of Sale

C.08.013. (1) Notwithstanding anything in this Division, a person may sell a new drug proposed for use in animals to an experimental studies investigator in a quantity specified by the Director for the purpose of conducting an experimental study in animals if
23-4-81 (a) the experimental studies investigator has been issued an experimental studies certificate pursuant to subsection C.08.015(1) and the certificate has not been suspended or cancelled pursuant to section C.08.018; and
(b) the drug is labelled in accordance with subsection C.08.016(1).

(2) For the purposes of this section and sections C.08.014 to C.08.018,
"experimental studies certificate" means a certificate issued pursuant to subsection C.08.015(1);
"experimental studies investigator" means a person named as the investigator in an experimental studies certificate;
"experimental study" means a limited test of a new drug in animals carried out by an experimental studies investigator.

Experimental Studies Certificate

C.08.014. (1) For the purpose of obtaining an experimental studies certificate, an applicant shall submit to the Director, in writing, the following information and material:

20-4-93
(a) the brand name of the new drug or the identifying name or code proposed for the new drug;
(b) the objectives and an outline of the proposed experimental study of the new drug;
(c) the species, number and production type of animals in respect of which the new drug is to be administered;
(d) the name and address of the manufacturer of the new drug;
(e) the address of the premises in which the experimental study is to be conducted;
(f) a description of the facilities to be used to conduct the experimental study;
(g) the name, address and qualifications of the proposed experimental studies investigator;
(h) the chemical structure, if known, and the relevant compositional characteristics of the new drug;
(i) the proposed quantity of the new drug to be used for the experimental study;
(j) the results of any toxicological or pharmacological studies that may have been conducted with the new drug;
(k) the written agreement referred to in subsection (2); and
(l) such other information and material as the Director may require.

(2) Where a food-producing animal is involved in an experimental study, the applicant referred to in subsection (1) shall, for the purposes of obtaining an experimental studies certificate, obtain from the owner of the animals, or from a person authorized by the owner, a written agreement not to sell the animal or any products from it without prior authorization from the experimental studies investigator.

(3) The Director may request the manufacturer of a new drug to submit to him samples of the new drug or of any ingredient of the drug and, in satisfactory form and manner, any other information that the Director requests and where such samples or information are not submitted, the Director may refuse to issu an experimental studies certificate.

C.08.015. (1) Where, on receipt of the information and material submitted pursuant to section C.08.014, the Director is satisfied that

23-4-81
(a) the applicant is qualified as an experimental studies investigator for the purposes of the proposed experimental study,
(b) the facilities for the conduct of the experimental study are adequate for the purposes of the proposed experimental study, and
(c) the proposed experimental study can be conducted without undue foreseeable risk to humans or animals,

the Director shall issue an experimental studies certificate for the purposes of the proposed experimental study and shall specify therein the quantity of the new drug that may be sold to the experimental studies investigator.

(2) Where, on receipt of the information and material submitted pursuant to section C.08.014, the Director is not satisfied that the requirements of paragraphs (1)(a), (b) and (c) have been met, he shall refuse to issue an experimental studies certificate.

Labelling

C.08.016. (1) The label of new drug that is sold pursuant to section C.08.013 shall show

20-4-93
(a) the brand name of the new drug or the identifying name or code proposed for the new drug;
(b) a warning statement to the effect that the drug is for use only in an experimental study in animals;
(c) the lot number of the drug;
(d) the name and address of the manufacturer of the drug; and
(e) the name of the person to whom the drug has been supplied.

21-7-88
(2) Sections C.01.004, C.01.005 and C.01.014 do not apply to a drug that is sold pursuant to section C.08.013 and labelled in accordance with subsection (1).

Conditions of Experimental Study

C.08.017. An experimental studies investigator shall

(a) use the new drug only in accordance with the outline of the experimental study;
7-6-01
(b) report immediately to the Director all serious adverse drug reactions associated with the use of the new drug;
(c) report promptly to the Director, on request, the results of the experimental study;

(d) return to the manufacturer, on request, all quantities of the new drug not used in the experimental study;
(e) maintain all records of the experimental study for a period of at least two years after the conclusion of the study and, on request, make such records available to the Director;
(f) report promptly to the Director any known disposition of animals involved in the study or of any products from the animals that is contrary to the terms of the agreement referred to in subsection C.08.014(2); and
(g) account to the Director, on request, for all quantities of the new drug received by him.

Suspension or Cancellation of Experimental Studies Certificate

C.08.018. (1) Where the Director is of the opinion that it is necessary in order to safeguard animal health or public health or to promote public safety, he may suspend for a definite or indefinite period or cancel an experimental studies certificate.

23-4-81

(2) Without limiting the generality of subsection (1), the Director may suspend or cancel an experimental studies certificate if

(a) the information and material submitted pursuant to section C.08.014 contains an untrue statement or contains any omission concerning the properties of the drug that were known or ought reasonably to have been known to the manufacturer or the experimental studies investigator;
(b) the labelling of the new drug is, at any time, false, misleading, deceptive or incomplete;
(c) the qualifications of the experimental studies investigator prove to be inadequate;
(d) there is evidence that the experimental studies investigator has not complied with the conditions referre to in section C.08.017; or
(e) an action of the manufacturer in respect of the new drug has resulted in his conviction for a violation of section C.08.002.

Non-prescription Drugs

C.09.001. This Division does not apply to

(a) a drug that is required by these Regulations or the Narcotic Control Regulations to be sold only on prescription, or
(b) a drug for use exclusively in animals.

Analgesics

General

C.09.010. No manufacturer or importer shall, after June 30, 1986, sell a drug for analgesia that contains a combination of

(a) a salt or derivative of salicylic acid with another salt or derivative of salicylic acid or with salicylamide; or
(b) acetaminophen with a salt or derivative of salicylic acid or with salicylamide.

29-5-86 **C.09.011.** Each label of a drug that is intended for internal use and contains acetaminophen, salicylic acid o a salt or derivative thereof shall, after June 30, 1986, carry a caution

(a) to consult a physician if the underlying condition requires continued use for more than five days; and
(b) that it is hazardous to exceed the maximum recommended dose unless advised by a physician.

2-2-84 **C.09.012.** Each label of a drug that is intended for internal use and contains salicylic acid or a salt or derivative thereof shall after June 30, 1986, carry a warning statement to consult a physician before taking the drug during the last three months of pregnancy or when nursing.

Acetaminophen

C.09.020. (1) The adult standard dosage unit of acetaminophen shall be 325 mg.

28-8-90 (2) The children's standard dosage units of acetaminophen shall be 80 mg or 160 mg.

C.09.021. (1) In this Division, "acetaminophen product" means a drug that contains

(a) acetaminophen as a single medicinal ingredient; or
(b) acetaminophen in combination with caffeine.

28-8-90 (2) No manufacturer or importer shall sell an acetaminophen product unless it meets the requirements of this Division.

(3) Revoked by P.C. 1990-1818 of August 28, 1990.

4-11-99 **C.09.022.** (1) Subject to subsections (2) to (4), an acetaminophen product sold in the form of a tablet, capsule or other solid dosage form intended for oral administration shall contain one adult standard dosage unit of acetaminophen per individual dosage form.

26-9-85 (2) An acetaminophen product in the form of a tablet, capsule or other solid dosage form intende for oral administration may contain 500 mg of acetaminophen per individual dosage form if it has a label that states that it is not a standard dosage unit product.

4-11-99 (3) An acetaminophen product sold in the form of a tablet, capsule or other solid dosage form tha is intended for oral administration may contain 325 mg of acetaminophen for immediate release and another 325 mg for subsequent release, if it has a label that states that it is not a standard dosage unit product.

(4) An acetaminophen product sold in the form of a tablet, capsule or other solid dosage form tha is intended for oral administration and that is specially recommended for children shall contain one children's standard dosage unit of acetaminophen per individual dosage form.

(5) An acetaminophen product in the form of a liquid that is intended to be taken as drops and that is specially recommended for children shall contain one children's standard dosage unit of acetaminophen per millilitre of the product.

4-11-99 (6) A package of an acetaminophen product described in subsection (5) shall be accompanied by a measuring device capable of accurately delivering 0.5 mL of the product.

(7) An acetaminophen product in the form of a liquid that is not intended to be taken as drops and that is specially recommended for children shall contain one children's standard dosage unit per teaspoon of the product.

(8) An acetaminophen product in the form of a liquid shall contain one adult standard dosage unit of acetaminophen per teaspoon of the product.

Salicylates

C.09.030. (1) The adult standard dosage unit of a salicylate shall be

(a) in the case of acetylsalicylic acid, sodium salicylate and magnesium salicylate, 325 mg; and
(b) in the case of choline salicylate, 435 mg.

(2) The children's standard dosage unit of a salicylate shall be

(a) in the case of acetylsalicylic acid, sodium salicylate and magnesium salicylate, 80 mg; and
(b) in the case of choline salicylate, 110 mg.

C.09.031. (1) In this Division, "salicylate product" means a drug that contains

(a) a salt or derivative of salicylic acid as a single medicinal ingredient;
(b) a salt or derivative of salicylic acid in combination with caffeine;
(c) a salt or derivative of salicylic acid in combination with one or more buffering agents or antacids; or
2-2-84 (d) a salt or derivative of salicylic acid in combination with caffeine and one or more buffering agents or antacids.

(2) No manufacturer or importer shall sell a salicylate product after June 30, 1986 unless it meets the requirements of this Division.

26-9-85 (3) No manufacturer or importer shall, until June 30, 1986, sell a salicylate product in a dosage unit other than one mentioned in this Division, unless the salicylate product was legally available for sale in Canada on February 1, 1984.

26-9-85 **C.09.032.** (1) Subject to subsections (2) and (3) and section C.09.035, a salicylate product in the form of a tablet, capsule or other solid dosage form intended for oral administration shall contain one adult standard dosage unit of a salicylate per individual dosage form.

(2) A salicylate product in the form of a tablet, capsule or other solid dosage form intended for oral administration may contain

(a) 500 mg of acetylsalicylic acid, sodium salicylate or magnesium salicylate, or
(b) 670 mg of choline salicylate

per individual dosage form if it has a label that states that it is not a standard dosage unit product.

(3) A salicylate product in the form of a tablet, capsule or other solid dosage form intended for oral administration may contain

(a) two adult standard dosage units of a salicylate per individual dosage form if the label of the salicylate product states that each individual dosage form contains two adult standard dosage units; and
(b) three adult standard dosage units of a salicylate per individual dosage form if the label of the salicylate product states that each individual dosage form contains three adult standard dosage units.

*(R) Minor correction

C.09.033. (1) Subject to subsection (2), a salicylate product in the form of a liquid shall contain one adult standard dosage unit of a salicylate per teaspoon.

(2) A salicylate product in the form of a liquid may contain

(a) two adult standard dosage units of a salicylate per teaspoon if the label of the salicylate product states that each teaspoon of the product contains two adult standard dosage units; and
(b) three adult standard dosage units of a salicylate per teaspoon if the label of the salicylate product states that each teaspoon of the product contains three adult standard dosage units.

2-2-84

C.09.034. A salicylate product that is claimed to be buffered shall provide at least 1.9 milliequivalents of acid neutralizing capacity per adult standard dosage unit of a salicylate.

C.09.035. A salicylate product in the form of a tablet, capsule or other solid dosage form intended for oral administration and that is specially recommended for children shall contain one children's standard dosage unit of a salicylate per individual dosage form.

DIVISION 10

Repealed by P.C. 1998-1461 of August 26, 1998.

SCHEDULE

Repealed by P.C. 1998-1461 of August 26, 1998.

TABLE

Repealed by P.C. 1998-1461 of August 26, 1998.

515, August 26, 1998
Replaces page 126H, April 20, 1993

*(R) Minor correction

VITAMINS, MINERALS AND AMINO ACIDS

DIVISION 1

D.01.001. (1) In this Part,

"**advertise**" means to advertise to the general public;

"**brand name**" means, with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French,

(a) that is assigned to the drug by its manufacturer,

(b) under which the drug is sold or advertised, and

20-4-93 (c) that is used to distinguish the drug; (*marque nominative*)

"**common name**" means, with reference to a salt or derivative of a vitamin, the name in English or French by which the salt or derivative is

(a) commonly known, and

(b) designated in scientific or technical journals; (*nom usuel*)

31-10-88 "**prepackaged product**" means any food that is contained in a package in the manner in which it is ordinarily sold to, or used or purchased by, a person; (*produit préemballé*)

"**reasonable daily intake**" in respect of a food named in an item in Column I of Schedule K1 means the amount of that food set out in Column II of that item;

"**recommended daily intake**" means, in respect of a vitamin or mineral nutrient, the amount of the vitamin or mineral nutrient set out in

14-5-96 (a) column II of Table I to Division 1 and column II of Table I to Division 2, for foods intended for persons 2 years of age or older, and

(b) column III of Table I to Division 1 and column III of Table I to Division 2, for foods intended for infants and children less than 2 years of age; (*apport quotidien recommandé*)

31-10-88 "**testimonial**" with respect to a food or drug that is represented as containing a vitamin, mineral nutrient or mineral means any dramatized or undramatized pictorial, written or oral representation as to the result that is, has been or may be produced by the addition to a person's diet of that vitamin, mineral nutrient or mineral, as the case may be.

14-5-96 "**weighted recommended nutrient intake**" means, in respect of a vitamin or mineral nutrient, the amount of the vitamin or mineral nutrient set out in Table II to Division 1 and Table II to Division 2. (*apport nutritionnel recommandé pondéré*)

(2) For the purposes of this Part, a serving of stated size of a food shall be

(a) expressed

31-10-88 (i) in grams, where the net quantity of the food is declared on the label by weight, and

(ii) in millilitres, where the net quantity of the food is declared on the label by volume; and

(b) where the food is packaged in a container that could reasonably be construed as containing a single serving of the food, equal to the net quantity of the food.

* (2) For the purposes of this Part, a serving of stated size of a food shall be

(a) based on the food as offered for sale; and

(b) expressed

(i) in grams, if

(A) the net quantity of the food is declared on the label by weight or by count, or

(B) the food is set out in column 1 of item 78, 149 or 150 of Schedule M, and

(ii) in millilitres, if the net quantity of the food is declared on the label by volume, except in the case of a food referred to in clause (i) (B).

12-12-02

(3) A serving of stated size shall be the net quantity of the food in the package if

(a) the quantity of food can reasonably be consumed by one person at a single eating occasion;

(b) the reference amount, as defined in section B.01.001, of the food is less than 100 g or 100 mL and the package contains less than 200% of that amount; or

(c) the reference amount, as defined in section B.01.001, of the food is 100 g or 100 mL or more and the package contains 150% or less of that amount.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

Vitamins in Foods

D.01.002. (1) In this Division, "vitamin" means any of the following vitamins:

(a) vitamin A;
(b) vitamin D;
(c) vitamin E;
(d) vitamin K;
(e) vitamin C;
(f) thiamin, thiamine or vitamin B_1;
(g) riboflavin or vitamin B_2;
31-10-88 (h) niacin;
(i) vitamin B_6;
(j) folacin;
12-12-02 * (j) folacin or folate;
(k) vitamin B_{12};
(l) pantothenic acid or pantothenate; and,
(m) biotin. (*vitamine*)

(2) For the purposes of this Division, no expression, other than an expression set out in subsection (1), shall be used to declare the vitamin content of a food.
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(3) This Division applies only in respect of foods represented as containing a vitamin for use in human nutrition.

29-11-90 **D.01.003.** (1) For the purposes of these Regulations, the vitamin content of a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, shall be determined

(a) in the case of vitamin A, in terms of the content of retinol and its derivatives and beta-carotene, expressed as retinol equivalents (RE) on the basis of the following relationships:
(i) 1 RE = 1 microgram retinol, and
(ii) 1 RE = 6 micrograms beta-carotene;
31-10-88 (b) in the case of vitamin D, in terms of the content of cholecalciferol and ergocalciferol, expressed in micrograms;
(c) in the case of vitamin E, in terms of the content of d-alpha-tocopherol and dl-alpha-tocopherol and their derivatives, expressed in milligrams on the basis of the following relationships:
(i) 1 milligram ***d***-alpha-tocopherol = 1 milligram vitamin E, and
(ii) 1 milligram ***dl***-alpha-tocopherol = 0.74 milligram vitamin E;
(d) in the case of vitamin K, in terms of the content of phylloquinone and menaquinones, expressed in micrograms;March 15, 2002
(e) in the case of vitamin C, in terms of the content of L-ascorbic acid and L-dehydroascorbic acid and their derivatives, calculated in milligram equivalents of L-ascorbic acid and expressed in milligrams;
29-11-90 (f) in the case of thiamin, thiamine or vitamin B_1 and its derivatives, in terms of the content of thiamin, expressed in milligrams;
(g) in the case of riboflavin or vitamin B_2 and its derivatives, in terms of the content of riboflavin, expressed in milligrams;
(h) in the case of niacin, in terms of the content of niacin and its derivatives, calculated in milligrams of nicotinic acid, plus the content of tryptophan, calculated in milligrams and divided by 60, with the total expressed as niacin equivalents (NE);
(i) in the case of vitamin B_6, in terms of the content of pyridoxine, pyrodoxal and pyridoxamine and their derivatives, calculated in milligram equivalents of pyridoxine and expressed in milligrams;

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

(j) in the case of folacin, in terms of the content of folic acid (pteroylmonoglutamic acid) and related compounds exhibiting the biological activity of folic acid, calculated in microgram equivalents of folic acid and expressed in micrograms;

(k) in the case of vitamin B_{12}, in terms of the content of cyanocobalamin and related compounds exhibiting the biological activity of cyanocobalamin, calculated in microgram equivalents of cyanocobalamin and expressed in micrograms;

(l) in the case of pantothenic acid or pantothenate, in terms of the content of ***d***-pantothenic acid, expressed in milligrams; and

31-10-88 (m) in the case of biotin, in terms of the content of biotin, expressed in milligrams.

(2) For the purpose of paragraph (1)(h), the content of tryptophan may be calculated

(a) where the protein originates from a food that contains protein from more than one source or from a source other than milk, meat, poultry, fish or eggs, as constituting 1.1 per cent of the protein;

(b) where the protein originates from milk, meat, poultry or fish, as constituting 1.3 per cent of the protein; and

(c) where the protein originates from eggs, as constituting 1.5 per cent of the protein.

D.01.004. (1) Subject to subsection (4), no person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim based on the vitamin content of the food unless

14-5-96 (a) the vitamin is a vitamin set out in column I of Table I to this Division;

(b) in the case of a claim, the percentage of the recommended daily intake of the vitamin, per serving of stated size, is 5 per cent or more; and

(c) the vitamin content of the food is declared as a percentage of the recommended daily intake of the vitamin, per serving of stated size.

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(2) For the purposes of paragraphs (1)(b) and (c), the percentage of the recommended daily intake of the vitamin shall be calculated

14-5-96 (a) subject to paragraph (b), as a function of the amount set out in column II of Table I to this Division for that vitamin; and

(b) where the food is intended for infants or children less than 2 years of age, as a function of the amount set out in column III of Table I to this Division for that vitamin.

29-11-90 (3) Paragraphs (1)(a) and (c) do not apply in respect of a statement of the biotin content as required by subparagraph B.24.202(a)(v).

14-5-96 (4) Where a vitamin, other than a vitamin set out in column I of Table I to this Division, is added to a food referred to in subsection (1), a statement of the content of that vitamin in the food may be made on the label of or in any advertisement for the food.

29-11-90 **D.01.005.** Where a vitamin has been added to a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, no person shall sell the food unless

14-5-96 (a) subject to paragraph (c), where the vitamin is set out in column I of Table I to this Division, the vitamin content of the food is declared in accordance with paragraph D.01.004(1)(c) and calculated in accordance with subsection D.01.004(2);

(b) subject to paragraph (c), where the vitamin is not set out in column I of Table I to this Division, the vitamin content of the food is declared in milligrams per serving of stated size; or

(c) where the food is sold solely for use as an ingredient in the manufacture of other foods, the vitamin content of the food is declared on the label of the food in accordance with section D.01.003 per 100 grams, per 100 millilitres, per gram or per millilitre of the food.

Sections D.01.004 and D.01.005 of the Regulations are replaced by the following:

***D.01.004.** (1) No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim concerning the vitamin content of the food unless

(a) the vitamin is set out in column I of Table I to this Division;
12-12-02 (b) the percentage of the recommended daily intake of the vitamin, per serving of stated size, is 5% or more; and
(c) the vitamin content is declared on the label or in the advertisement as a percentage of the daily value, per serving of stated size.

(2) If a statement or claim described in subsection (1) is made in an advertisement for a food that is not a prepackaged product or in an advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the percentage of the daily value, per serving of stated size, shall,

(a) in the case of an advertisement, other than a radio or television advertisement, be
  (i) adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and
  (ii) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once;
(b) in the case of a radio advertisement or the audio portion of a television advertisement, immediately precede or follow the statement or claim; or
(c) in the case of a television advertisement, be communicated
  (i) in the audio mode, if the statement or claim is made only in the audio portion of the advertisement or in both the audio and visual portions, or
  (ii) in the audio or visual mode, if the statement or claim is made only in the visual portion of the advertisement.

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(3) The percentage of the daily value, per serving of stated size, that is communicated in the visual mode of a television advertisement in accordance with subparagraph (2)(c)(ii) shall

(a) appear concurrently with and for at least the same amount of time as the statement or claim;
(b) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and
(c) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

(4) Paragraph (1)(b) does not apply in respect of a declaration of the vitamin content in a nutrition facts table.

(5) Paragraph (1)(c) does not apply in respect of a declaration of the biotin content as required by subparagraph B.24.202(a)(v).

D.01.006. No person shall, on the label of or in any advertisement for a food, make any claim concerning the action or effects of a vitamin contained in the food, except to the effect that the vitamin

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(a) is a factor in the maintenance of good health; and
(b) is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

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D.01.007. (1) Where a component of an ingredient of a prepackaged product referred to in the table to subsection B.01.009(1) is a vitamin, no person shall, on the label of the prepackaged product, declare the vitamin as a component of that ingredient unless

(a) the vitamin is declared by its common name within parentheses immediately following the declaration of the ingredient;
(b) the total content of the vitamin in the prepackaged product is declared in accordance with section D.01.005; and
(c) all components of the ingredient are declared.

(2) Paragraphs (1)(b) and (c) do not apply in respect of the ingredient "enriched flour".

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* **D.01.007.** (1) If a component of an ingredient of a prepackaged product set out in the table to subsection B.01.009(1) is a vitamin, no person shall, on the label of or in any advertisement for the prepackaged product, make a statement or claim concerning the vitamin as a component of that ingredient unless

(a) despite subsection B.01.008(6), the vitamin is declared by its common name immediately following the declaration of the ingredient in such a manner as to indicate that it is a component of that ingredient; and
(b) all components of the ingredient are declared.

(2) Paragraph (1)(b) does not apply to flour used as an ingredient in the manufacture of a prepackaged product referred to in subsection (1).

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D.01.008. Revoked by P.C. 1988-2457 of October 31, 1988

D.01.009. Subject to section D.01.010, no person shall sell a food to which any of the following vitamins have been added unless a reasonable daily intake of that food by a person would result in the daily intake by such person of not less than,

(a) in the case of vitamin A, 1,600 International Units;
(b) in the case of thiamine, 0.6 milligram;
(c) in the case of riboflavin, 1.0 milligram;
(d) in the case of niacin or niacinamide, 6 milligrams;
(e) in the case of ascorbic acid, 20 milligrams; and
(f) in the case of vitamin D, 300 International Units.

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

D.01.010. Where a food to which a vitamin has been added is represented as being solely for use in the feeding of children under two years of age, no person shall sell such food unless a reasonable daily intake of that food by a child under two years of age would result in the daily intake by the child of not less than,

(a) in the case of vitamin A, 1,000 International Units;
(b) in the case of thiamine, 0.4 milligram;
(c) in the case of riboflavin, 0.6 milligram;
(d) in the case of niacin or niacinamide, 4 milligrams;
(e) in the case of pyridoxine, 0.6 milligram;
(f) in the case of ascorbic acid, 20 milligrams;
(g) in the case of vitamin D, 300 International Units; and
(h) in the case of vitamin E, 5 International Units.

D.01.011. No person shall sell a food to which any of the following vitamins have been added if a reasonable daily intake of that food by a person would result in the daily intake by such person of more than,

(a) in the case of vitamin A, 2,500 International Units;
(b) in the case of thiamine, 2 milligrams;
(c) in the case of riboflavin, 3 milligrams;
(d) in the case of niacin or niacinamide 20 milligrams;
(e) in the case of pyridoxine, 1.5 milligrams;
(f) in the case of ascorbic acid, 60 milligrams;
(g) in the case of vitamin D, 400 International Units; and
(h) in the case of vitamin E, 15 International Units.

D.01.012. No person shall, in advertising a food that is represented as containing a vitamin or on a label of such food,

(a) give any assurance or guarantee of any kind with respect to the result that may be, has been or will be obtained by the addition of the vitamin to a person's diet; or
(b) refer to, reproduce or quote any testimonial.

D.01.013. The information required in a declaration referred to in section D.01.004 or D.01.005 shall be

(a) grouped together in a prominent and readily discernible manner; and
30-1-88 (b) given
(i) on the label, where the statement or claim is made on the label, or
(ii) in the advertisement or on the label, where the statement or claim is made in an advertisement.

12-12-02 ***D.01.013.** Repealed by P.C. 2002-2200 of December 12, 2002.

* **Coming into force:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;
b) a statement or claim set out in column 1 of the table following section B.01.603; or
c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

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TABLE I

RECOMMENDED DAILY INTAKE

	Item	Column I Vitamin	Units*	Column II Intake of persons 2 years of age or older	Column III Intake of infants or children less than 2 years of age
	1.	Vitamin A	(RE)	1000	400
30-1-88	2.	Vitamin D	(µg)	5	10
	3.	Vitamin E	(mg)	10	3
	4.	Vitamin C	(mg)	60	20
	5.	Thiamin, thiamine or vitamin B_1	(mg)	1.3	0.45
	6.	Riboflavin or vitamin B_2	(mg)	1.6	0.55
	7.	Niacin	(NE)	23	8
	8.	Vitamin B_6	(mg)	1.8	0.7
	9.	Folacin	(µg)	220	65
12-12-02	*9.	Folacin or folate	(µg)	220	65
	10.	Vitamin B_{12}	(µg)	2	0.3
	11.	Pantothenic acid or pantothenate	(mg)	7	2
12-12-02	*12.	Vitamin K	(µg)	80	30
	*13.	Biotin	(µg)	30	8

* RE = retinol equivalents
mg = milligrams
µg = micrograms
NE = niacin equivalents

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

*(R) Minor correction

TABLE II

WEIGHTED RECOMMENDED NUTRIENT INTAKE

Item	*Column I* *Vitamin*	*Column II* *Units*	*Column III* *Amount*
1.	Biotin	micrograms	90
2.	Folacin	micrograms	195
3.	Niacin	niacin equivalents	16
4.	Pantothenic Acid	milligrams	5.0
5.	Riboflavin	milligrams	1.2
6.	Thiamine	milligrams	1.0
7.	Vitamin A	retinol equivalents	870
8.	Vitamin B_6	milligrams	1.0
9.	Vitamin B_{12}	micrograms	1.0
10.	Vitamin C	milligrams	34
11.	Vitamin D	micrograms	3.0
12.	Vitamin E	milligrams	7.0

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*(R) Minor correction

Mineral Nutrients in Foods

D.02.001. (1) In this Division, "mineral nutrient" means any of the following chemical elements, whether alone or in a compound with one or more other chemical elements:

(a) sodium;
(b) potassium;
(c) calcium;
(d) phosphorus;
(e) magnesium;
(f) iron;
(g) zinc;
(h) iodide;
(i) chloride;
(j) copper;
(k) fluoride;
31-10-88 (l) manganese;
(m) chromium;
(n) selenium;
(o) cobalt;
(p) molybdenum;
(q) tin;
(r) vanadium;
(s) silicon; and
(t) nickel. (*minéral nutritif*)

(2) This Division applies only in respect of foods that are represented as containing a mineral nutrient for use in human nutrition.

D.02.002. (1) Subject to subsection (5), no person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim based on the mineral nutrient content of the food unless

14-5-96 (a) the mineral nutrient is a mineral nutrient set out in column I of Table I to this Division;
(b) in the case of a claim, the percentage of the recommended daily intake of the mineral nutrient, per serving of stated size, is 5 per cent or more; and
(c) the mineral nutrient content of the food is declared as a percentage of the recommended daily intake of the mineral nutrient, per serving of stated size.

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(2) For the purposes of paragraphs (1)(b) and (c), the percentage of the recommended daily intake of the mineral nutrient shall be calculated

14-5-96 (a) subject to paragraph (b), as a function of the amount set out in column II of Table I to this Division for that mineral nutrient; and
(b) where the food is intended for infants or children less than 2 years of age, as a function of the amount set out in column III of Table I to this Division for that mineral nutrient.

31-10-88 (3) Subsection (1) des not apply in respect of a statement or claim made in respect of sodium or potassium.

29-11-90 (4) Paragraphs 1(a) and (c) do not apply in respect of a statement of the fluoride ion content as required by sections B.12.002 and B.12.008 and in respect of a statement of the copper and manganese content as required by subparagraph B.24.202(a)(v).

14-5-96 (5) Where a mineral nutrient, other than a mineral nutrient set out in column I of Table I to this Division, is added to a food referred to in subsection (1), a statement of the mineral nutrient content of the food may be made on the label of or in any advertisement for the food.

D.02.003. Where a mineral nutrient has been added to a food, other than salt for table or general household use, a formulated liquid diet, a human milk substitute, a food represented as containing a human milk substitute, a mineral water or a spring water, no person shall sell the food unless

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(a) subject to paragraph (c), where the mineral nutrient is set out in column I of Table I to this Division, the mineral nutrient content of the food is declared in accordance with paragraph D.02.002(1)(c) and calculated in accordance with subsection D.02.002(2);

(b) subject to paragraph (c), where the mineral nutrient is not set out in column I of Table I to this Division, the mineral nutrient content is declared in milligrams per serving of stated size; or

(c) where the food is sold solely for use as an ingredient in the manufacture of other foods, the mineral nutrient content of the food is declared on the label of the food in milligrams per 100 grams, per 100 millilitres, per gram or per millilitre of the food.

Sections D.02.002 and D.02.003 of the Regulations are replaced by the following:

***D.02.002.** (1) No person shall, on the label of or in any advertisement for a food, other than salt for table or general household use containing added iodide, prepackaged water and ice, a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim concerning the mineral nutrient content of the food unless

(a) the mineral nutrient is set out in column I of Table I to this Division;

(b) the percentage of the recommended daily intake of the mineral nutrient, per serving of stated size, is 5% or more; and

(c) the mineral nutrient content is declared on the label or in the advertisement as a percentage of the daily value, per serving of stated size.

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(2) If a statement or claim described in subsection (1) is made in an advertisement for a food that is not a prepackaged product or in an advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the percentage of the daily value, per serving of stated size, shall,

(a) in the case of an advertisement, other than a radio or television advertisement, be

(i) adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and

(ii) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once;

(b) in the case of a radio advertisement or the audio portion of a television advertisement, immediately precede or follow the statement or claim; or

(c) in the case of a television advertisement, be communicated

(i) in the audio mode, if the statement or claim is made only in the audio portion of the advertisement or in both the audio and visual portions, or

(ii) in the audio or visual mode, if the statement or claim is made only in the visual portion of the advertisement.

* **Coming into force:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

(3) The percentage of the daily value, per serving of stated size, that is communicated in the visual mode of a television advertisement in accordance with subparagraph (2)(c)(ii) shall

(a) appear concurrently with and for at least the same amount of time as the statement or claim;
(b) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and
(c) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

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(4) Subsection (1) does not apply to a statement or claim made in respect of the sodium or potassium content.

(5) Paragraphs (1)(a) and (c) do not apply in respect of a declaration of the total fluoride ion content as required by sections B.12.002 and B.12.008.

(6) Paragraph (1)(b) does not apply in respect of a declaration of the mineral nutrient content in a nutrition facts table.

(7) Paragraph (1)(c) does not apply in respect of a declaration of the chromium, copper, manganese, molybdenum and selenium content as required by subparagraph B.24.202(a)(v).

D.02.004. No person shall, on the label of or in any advertisement for a food, make any claim concerning the action or effects of a mineral nutrient contained in the food, except to the effect that the mineral nutrient

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(a) is a factor in the maintenance of good health; and
(b) is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.

D.02.005. (1) Where a component of an ingredient of a prepackaged product referred to in the table to subsection B.01.009(1) is a mineral nutrient, no person shall, on the label of the prepackaged product, declare the mineral nutrient as a component of that ingredient unless

(a) the mineral nutrient is declared by its common name within parentheses immediately following the declaration of the ingredient;
(b) the total content of the mineral nutrient in the prepackaged product is declared in accordance with section D.02.003; and
(c) all components of the ingredient are declared.

(2) Paragraphs (1)(b) and (c) do not apply in respect of the ingredient "enriched flour".

D.02.006. The information required in a declaration referred to in section D.02.002 or D.02.003 shall be

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(a) grouped together in a prominent and readily discernible manner; and
(b) given
  (i) on the label, where the statement or claim is made on the label, or
  (ii) in the advertisement or on the label, where the statement or claim is made in an advertisement.

Sections D.02.005 and D.02.006 of the Regulations are replaced by the following:

***D.02.005.** (1) If a component of an ingredient of a prepackaged product set out in the table to subsection B.01.009(1) is a mineral nutrient, no person shall, on the label of or in any advertisement for the prepackaged product, make a statement or claim concerning the mineral nutrient as a component of that ingredient unless

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(a) despite subsection B.01.008(6), the mineral nutrient is declared by its common name immediately following the declaration of the ingredient in such a manner as to indicate that it is a component of that ingredient; and

(b) all components of the ingredient are declared.

(2) Paragraph (1)(b) does not apply to flour used as an ingredient in the manufacture of a prepackaged product referred to in subsection (1).

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TABLE I

RECOMMENDED DAILY INTAKE

	Column I			Column II	Column III
	Item	*Mineral Nutrient*	*Units**	*Intake of persons 2 years of age or older*	*Intake of infants and children less than 2 years of age*
31-10-88					
	1.	Calcium	(mg)	1100	500
	2.	Phosphorus	(mg)	1100	500
	3.	Magnesium	(mg)	250	55
	4.	Iron	(mg)	14	7
	5.	Zinc	(mg)	9	4
	6.	Iodide	(µg)	160	55
	*7.	Selenium	(µg)	50	15
	*8.	Copper	(mg)	2	0.5
12-12-02	*9.	Manganese	(mg)	2	1.2
	*10.	Chromium	(µg)	120	12
	*11.	Molybdenum	(µg)	75	15
	*12.	Chloride	(mg)	3400	1000

* mg = milligrams
µg = micrograms

* **COMING INTO FORCE:** *These requirements come into force on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts", "valeur nutritive" or "valeurs nutritives".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

TABLE II

WEIGHTED RECOMMENDED NUTRIENT INTAKE

	Column I	*Column II*	*Column III*
Item	*Mineral Nutrient*	*Units*	*Amount*
1.	Calcium	milligrams	780
2.	Iodide	micrograms	155
3.	Iron	milligrams	10
4.	Phosphorus	milligrams	885
5.	Magnesium	milligrams	210
6.	Zinc	milligrams	10

14-5-96

31-10-88 **D.02.007.** Revoked by P.C. 1988-2457 of October 31, 1988

D.02.008. No person shall, in advertising a food that is represented as containing a mineral nutrient or on a label of such food,

(a) give any assurance or guarantee of any kind with respect to the result that may be, has been or will be obtained by the addition of the mineral nutrient to a person's diet, or

(b) refer to, reproduce or quote any testimonial.

D.02.009. No person shall sell a food to which any of the following mineral nutrients have been added unless a reasonable daily intake of that food by a person would result in the daily intake by such person of not less than,

(a) in the case of calcium, 300 milligrams;
(b) in the case of phosphorus, 300 milligrams;
(c) in the case of iron, 4 milligrams; and
(d) in the case of iodine, 0.10 milligram.

D.02.010. (1) No person shall sell elemental iron powder for use in foods as a source of iron as a mineral nutrient unless

(a) subject to paragraph (b), the powder meets the specifications for
  (i) Iron, Carbonyl,
  (ii) Iron, Electrolytic, or
  (iii) Iron, Reduced,
  as set out in the *Food Chemicals Codex, Third Edition, 1981*, published by the National Academy of Sciences of the United States of America; and

(b) in the case of Iron, Reduced, 100 per cent by weight of the particles pass through a 100 mesh sieve and at least 95 per cent by weight of the particles pass through a 325 mesh sieve.

12-4-84

(2) No person shall sell a food to which elemental iron powder has been added as a source of iron as a mineral nutrient unless the powder meets the requirements referred to in paragraphs (1)(a) and (b).

D.02.011. No person shall sell a food to which sodium iron pyrophosphate has been added as a source of iron as a mineral nutrient unless

(a) the bioavailability of the iron in the food is not less than 50 per cent of the bioavailability of ferrous sulphate as determined by official method FO-42, Determination of Bioavailability of Iron, December 15, 1982; and

(b) that person retains documentary evidence showing that the bioavailability of the iron in the food has been determined by the official method referred to in paragraph (a) and, on request by the Director, submits such evidence to the Director.

25-8-76 **Addition of Vitamins, Mineral Nutrients or Amino Acids to Foods**

D.03.001. (1) In this Division, the expressions "vitamin" and "mineral nutrient" have the same meaning as in Divisions 1 and 2.

31-10-88 (2) This Division applies only in respect of foods that are represented as containing a vitamin, mineral nutrient or amino acid for use in human nutrition.

D.03.002. (1) Subject to section D.03.003, no person shall sell a food to which a vitamin, mineral nutrient or amino acid has been added unless the food is listed in Column I of the Table to this section and the vitamin, mineral nutrient or amino acid, as the case may be, is listed opposite that food in Column II of the Table.

27-6-85 (2) No milk or milk product or derivative listed in column I of the Table to this section applies to the lacteal secretion obtained from the mammary gland of any animal other than a cow, genus Bos, or a product or derivative of such secretion unless that animal is identified therein.

25-8-76 **TABLE**

		Column I *Food*	*Column II* *Vitamin, Mineral Nutrient or Amino Acid*
9-3-89	1.	Breakfast cereals	Thiamine, niacin, vitamin B_6, folic acid, pantothenic acid, magnesium, iron and zinc.
	2.	Fruit nectars, vegetable drinks, bases and mixes for vegetable drinks and a mixture of vegetable juices.	Vitamin C.
18-5-78	2.1	Fruit flavoured drinks that meet all the requirements of section B.11.150	Vitamin C, folic acid, thiamine, iron, potassium.
	2.2	Bases, concentrates and mixes that are used for making fruit flavoured drinks and that meet all the requirements of section B.11.151.	Vitamin C, folic acid, thiamine, iron, potassium.
	3.	Infant cereal products	Thiamine, riboflavin, niacin or niacinamide, calcium, phosphorus, iron, iodine.
8-1-81	4.	Margarine and other similar substitutes for butter	Vitamin A, Vitamin D, alpha-tocopherol.
1-11-94	5.	Alimentary pastes	Thiamine, riboflavin, niacin or niacinamide, folic acid, pantothenic acid, vitamin B_6, iron, magnesium.
12-1-78	6.	Infant formulas and formulated liquid diets	Amino acids - alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine; Minerals - calcium, chloride, chromium, copper, iodide, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc; Vitamins - alpha-tocopherol, biotin, d-pantothenic acid, folic acid, niacin, riboflavin, thiamin, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin K.
10-11-76			
31-10-88			

*(R) Minor correction

		Column I Food	Column II Vitamin, Mineral Nutrient or Amino acid
13-1-94	6.1	Foods represented for use in a very low energy diet	Vitamins - alpha-tocopherol, biotin, d-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin K Minerals - calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus,potassium, selenium, sodium, zinc.
	7.	Flavoured beverage mixes and bases recommended for addition to milk	Vitamin A, thiamine, niacin or niacinamide, vitamin C, iron.
28-1-75	8.	Simulated meat products, simulated poultry meat products, meat product extenders and poultry product extenders	Thiamine, riboflavin, niacin, pyridoxine, *d*-pantothenic acid, folic acid, vitamin B_{12}, iron, magnesium, potassium, zinc, copper, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine.
3-10-95	9.	Meal replacements and nutritional supplements	Vitamins - alpha-tocopherol, biotin, d-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D Minerals - calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc
30-8-78	9.1	Ready breakfast, instant breakfast and other similar breakfast replacement foods however described	Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin C, iron.
	10.	Condensed milk, milk, milk powder, sterilized milk, (naming the flavour) milk	Vitamin D.
13-5-75	11.	Skim milk with added milk solids, partly skimmed milk with added milk solids, (naming the flavour) skim milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk with added milk solids, (naming the flavour) partly skimmed milk with added milk solids, skim milk, partly skimmed milk, skim milk powder	Vitamin A, vitamin D.
	12.	Evaporated milk	Vitamin C, vitamin D.
	13.	Evaporated skim milk, concentrated skim milk, evaporated partly skimmed milk, concentrated partly skimmed milk	Vitamin A, vitamin C, vitamin D.
6-4-89	14.	Apple juice, reconstituted apple juice, grape juice, reconstituted grape juice, pineapple juice, reconstituted pineapple juice, apple and (naming the fruit) juice as described in section B.11.132, concentrated fruit juice except frozen concentrated orange juice	Vitamin C.
	15.	Flour, white flour, enriched flour or enriched white flour	Thiamine, riboflavin, niacin, vitamin B_6, folic acid, d-pantothenic acid, calcium, iron, magnesium.
1-11-94	16.	Revoked by P.C. 1994-1820 of November 1, 1994	
	17.	Table salt, table salt substitutes	Iodine.
23-1-74	18.	Dehydrated potatoes	Vitamin C.

*(R) Minor correction

		Column I Food	Column II Vitamin, Mineral Nutrient or Amino acid
28-4-77	19.	Products simulating whole egg	Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin B_6, *d*-pantothenic acid, folic acid, vitamin B_{12}, alpha-tocopherol, calcium, iron, zinc, potassium.
29-11-90	20.	Revoked by P.C. 1990-2554 of November 29, 1990	
	21.	Goat's milk, goat's milk powder	Vitamin D.
	22.	Partly skimmed goat's milk, skimmed goat's milk, partly skimmed goat's milk powder, skimmed goat's milk powder	Vitamin A and D.
27-6-85	23.	Evaporated goat's milk	Vitamins C, D, folic acid.
	24.	Evaporated partly skimmed goat's milk, evaporated skimmed goat's milk	Vitamins A, C, D, folic acid.
13-3-86	25.	Pre-cooked rice as defined in subsection B.13.010.1(1)	Thiamine, niacin, vitamin B_6, folic acid, pantothenic acid, iron
6-11-87	26.	Mineral water, spring water, water in sealed containers, prepackaged ice	Fluorine.
14-5-96	27.	Liquid whole egg, dried whole egg, frozen whole egg, liquid yolk, dried yolk, frozen yolk, liquid egg white, (liquid albumen), dried egg white (dried albumen), frozen egg white (frozen albumen), liquid whole egg mix, dried whole egg mix, frozen whole egg mix, liquid yolk mix, dried yolk mix, frozen yolk mix	Vitamin A, Vitamin D, Vitamin E, thiamine, riboflavin, niacin, vitamin B_6, folacin, vitamin B_{12}, pantothenic acid, calcium, phosphorus, magnesium, potassium, iron, zinc

29-11-90 **D.03.003.** Section D.03.002 does not apply to a food when all of the following conditions are met:

(a) the food is

13-9-95 (i) a gluten-free food referred to in paragraph B.24.003(1)(g), or

(ii) represented for a special dietary use referred to in paragraph B.24.003(1)(h) or (i);

29-11-90 (b) no standard is prescribed in these Regulations for the food; and

(c) the food is not advertised.

*(R) Minor correction

Division 4 of Part D is repealed effective January 1, 2004 by P.C. 2003-847 of June 5, 2003.

Minerals in Drugs

Sections D.05.001 to D.05.007 are repealed effective January 1, 2004 by P.C. 2003-847 of June 5, 2003.

26-2-81

D.05.008. (1) Subject to subsection (2), no person shall sell a drug containing fluorine if the largest recommended daily dosage of that drug as shown on the label thereof would, if consumed by a person, result in a daily intake by that person of more than one milligram of fluoride ion.

(2) Subsection (1) does not apply to a drug sold by prescription.

D.05.009. Where a drug contains fluorine, both the inner and outer labels of the drug shall carry a cautionary statement that, if the drug is used in an area where the drinking water has a natural fluorine content in excess of 0.7 parts of fluoride ion per million parts of water or is artificially fluoridated, mottling of the tooth enamel of a user of the drug may result.

Section D.05.010 is repealed effective January 1, 2004 by P.C. 2003-847 of June 5, 2003.

SCHEDULE K

REASONABLE DAILY INTAKE FOR VARIOUS FOODS

	Column I *Name and Description*	*Column II* *R.D.I.*	
	1. Alimentary Pastes, dry	3.0 oz	85.0 g
	2. Bacon (side) simulated meat product that resembles side bacon, (cooked)	1.0 oz	28.0 g
	3. Beverage Bases and Mixes, Flavoured, for Addition to Milk (ready to serve)	16.0 fl oz	454.0 ml
	4. Bread, 5 slices	5.3 oz	150.0 g
	5. Butter	2.0 oz	57.0 g
	6. Buttermilk	30.0 fl oz	852.0 ml
28-1-75	7. Cereals, Breakfast or Infant	1.0 oz	28.0 g
	8. Cereals, puffed	0.5 oz	14.0 g
	9. Cheese (other than Cottage Cheese)	2.0 oz	57.0 g
	10. Cheese, Cottage	3.5 oz	100.0 g
	11. Condensed Milk	15.0 fl oz	426.0 ml
	12. Cream, whipping	2.0 oz	57.0 g
	13. Egg, yolk-replaced egg	3.5 oz	100.0 g
	14. Evaporated Milk, Evaporated Skim Milk, Evaporated Partly Skimmed Milk	30.0 fl oz	852.0 ml
12-1-78		(reconstituted to original volume)	
	15. Fish, Shell Fish	3.5 oz	100.0 g
	16. Fruits, dried	2.0 oz	57.0 g
	17. Fruits, (other than banana, lemon, lime, watermelon)	3.5 oz	100.0 g
	18. Fruits, Banana	5.3 oz	150.0 g
	19. Fruits, Lemon	1.8 oz	50.0 g
	20. Fruits, Lime	1.8 oz	50.0 g
	21. Fruits, Watermelon	7.0 oz	200.0 g
	22. Fruit Drinks, Fruit Nectars (ready to serve)	4.0 fl oz	114.0 g
	23. Fruit Drink Bases, Mixes and Concentrates (ready to serve)	4.0 fl oz	114.0 g
	24. Fruit Juices (other than lemon juice and lime juice)	4.0 fl oz	114.0 g
	25. Fruit Juices, Lemon	1.0 fl oz	28.0 ml
	26. Fruit Juices, Lime	1.0 fl oz	28.0 ml
	27. Ice Cream, Ice Milk	3.5 oz	100.0 g
28-1-75	28. Infant Formulas, Prepared (ready to serve)	As directed by Label	
	29. Instant Breakfast, Ready Breakfast (ready to serve)	As directed by Label	
	30. Margarine	2.0 oz	57.0 g
	31. Meat Products	3.5 oz	100.0 g
28-1-75	32. Meat Product Extenders	3.5 oz	100.0 g
	33. Extended Meat Products	3.5 oz	100.0 g
	34. Milk, whole	30.0 fl oz	852.0 ml
	35. Milk Powder (reconstituted and ready to serve)	30.0 fl oz	852.0 ml
12-4-84	36. (naming the flavour) Milk	30.0 fl oz	852.0 ml
	37. Molasses	1.5 oz	43.0 g
	38. Nuts	1.0 oz	28.0 g
	39. Peanut Butter	1.0 oz	28.0 g
	40. Poultry Products	3.5 oz	100.0 g
	41. Extended Poultry Products	3.5 oz	100.0 g
	42. Poultry Product Extenders	3.5 oz	100.0 g
	43. Simulated Meat Products excluding a simulated meat product that resembles side bacon	3.5 oz	100.0 g
	44. Simulated Poultry Products	3.5 oz	100.0 g
	45. Skim Milk, Partly Skimmed Milk	30.0 fl oz	852.0 ml
12-4-84	46. (naming the flavour) Skim Milk, (naming the flavour) Partly Skimmed Milk	30.0 fl oz	852.0 ml

*(R) Minor correction

REASONABLE DAILY INTAKE FOR VARIOUS FOODS

Column I *Name and Description*	*Column II* *R.D.I.*	
47. Skim Milk Powder, Partly Skimmed Milk Powder (reconstituted) and (ready to serve)	30.0 fl oz	852.0 ml
48. Skim Milk with Added Milk Solids, Partly Skimmed Milk with Added Milk Solids	30.0 fl oz	852.0 ml
49. (naming the flavour) Skim Milk with Added Milk Solids, (naming the flavour) Partly Skimmed Milk with Added Milk Solids	30.0 fl oz	852.0 ml
50. Soup (ready to serve)	7.0 fl oz	200.0 ml
51. Sterilized Milk	30.0 fl oz	852.0 ml
52. Vegetable Juices	4.0 fl oz	114.0 ml
53. Vegetable Drinks	4.0 fl oz	114.0 ml
54. Vegetable Drink Concentrates, Mixes and Bases (ready to serve)	4.0 fl oz	114.0 ml
55. Vegetable (other than baked beans and cooked potatoes)	3.5 oz	100.0 g
56. Vegetables, baked beans	8.5 oz	250.0 g
57. Vegetables, cooked potatoes	7.0 oz	200.0 g
58. Yeast	0.5 oz	14.0 g
59. Yogurt, plain	5.0 oz	150.0 g

*(R) Minor correction

*** SCHEDULE M**
(Sections B.01.001, B.01.002A and D.01.001)

REFERENCE AMOUNTS

*** SCHEDULE M COMES INTO FORCE** *on December 12, 2002 if the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacture of the product, contains:*

a) a statement or claim set out in column 4 of any items 15, 16 and 22 to 26 of the table following section B.01.513;

b) a statement or claim set out in column 1 of the table following section B.01.603; or

c) the expression "nutrition facts ", "valeur nutritive " or " valeurs nutritives ".

Otherwise, it comes into force on December 12, 2005.

For small manufacturers who had gross revenues from sales in Canada of food of less than one million dollars for the 12-month period prior to December 12, 2002, comes into force on December 12, 2007.

Item	Column 1 Food	Column 2 Reference amount[1]
	Bakery Products	
1	Bread, excluding sweet quick-type rolls	50 g
2	Bagels, tea biscuits, scones, rolls, buns, croissants, tortillas, soft bread sticks, soft pretzels and corn bread	55 g
3	Brownies	40 g
4	Heavy weight cake: 10 g or more per 2.5 cm cube, such as cheese cake, pineapple upside-down cake, cake with at least 35% of the finished weight as fruit, nuts or vegetables, or any of these combined	125 g
5	Medium weight cake: 4 g or more per 2.5 cm cube but less than 10 g per 2.5 cm cube, such as cake with or without icing or filling, cake with less than 35% of the finished weight as fruit, nuts or vegetables or any of these combined, light weight cake with icing, Boston cream pie, cupcakes, eclairs or cream puffs	80 g
6	Light weight cake: less than 4 g per 2.5 cm cube, such as angel food, chiffon or sponge cake, without icing or filling	55 g
7	Coffee cakes, doughnuts, danishes, sweet rolls, sweet quick-type breads and muffins	55 g
8	Cookies, with or without coating or filling, and graham wafers	30 g
9	Crackers, hard bread sticks and melba toast	20 g
10	Dry breads, matzo and rusks	30 g
11	Flaky type pastries, with or without filling or icing	55 g
12	Toaster pastries	55 g
13	Ice cream cones	5 g
14	Croutons	7 g
15	French toast, pancakes and waffles	75 g
16	Grain-based bars, with filling or partial or full coating	40 g
17	Grain-based bars, without filling or coating	30 g

Item	Column 1 Food	Column 2 Reference amount[1]
18	Rice cakes and corn cakes	15 g
19	Pies, tarts, cobblers, turnovers and other pastries	110 g
20	Pie crust	1/6 of 20 cm crust or 1/8 of 23 cm crust
21	Pizza crust	55 g
22	Taco shell, hard	30 g
	Beverages	
23	Carbonated and non-carbonated beverages, iced tea and wine coolers	355 mL
24	Sports drinks and water	500 mL
25	Coffee: regular, instant and specialty, including espresso, café au lait, flavoured and sweetened	175 mL
26	Tea and herbal tea (a) regular and instant (hot) (b) flavoured and sweetened, prepared from mixes	 175 mL 250 mL
27	Cocoa and chocolate beverages (hot)	175 mL
	Cereals and Other Grain Products	
28	Hot breakfast cereals, such as oatmeal or cream of wheat	40 g dry 250 mL prepared
29	Ready-to-eat breakfast cereals, puffed and uncoated (less than 20 g per 250 mL)	15 g
30	Ready-to-eat breakfast cereals, puffed and coated, flaked, extruded, without fruit or nuts (20 g to 42 g per 250 mL), very high fibre cereals (with 28 g or more fibre per 100 g)	30 g
31	Ready-to-eat breakfast cereals, fruit and nut type, granola (43 g or more per 250 mL) and biscuit type cereals	55 g
32	Bran and wheat germ	15 g
33	Flours, including cornmeal	30 g
34	Grains, such as rice or barley	45 g dry 140 g cooked
35	Pastas without sauce	85 g dry 215 g cooked
36	Pastas, dry and ready-to-eat, such as fried canned chow mein noodles	25 g
37	Starch, such as cornstarch, potato starch, tapioca starch or wheat starch	10 g
38	Stuffing	100 g

Item	Column 1 Food	Column 2 Reference amount[1]
	Dairy Products and Substitutes	
39	Cheese, including cream cheese and cheese spread, except those listed as a separate item	30 g
40	Cottage cheese	125 g
41	Cheese used as an ingredient, such as dry cottage cheese or ricotta cheese	55 g
42	Hard cheese, grated, such as parmesan or romano	15 g
43	Quark, fresh cheese and fresh dairy desserts	100 g
44	Cream and cream substitute, except those listed as a separate item	15 mL
45	Cream and cream substitute, powder	2 g
46	Cream and cream substitute, aerosol or whipped	15 g
47	Eggnog	125 mL
48	Milk, evaporated or condensed	15 mL
49	Plant-based beverages, milk, buttermilk and milk-based drinks, such as chocolate milk	250 mL
50	Shakes and shake substitutes, such as dairy shake mix	250 mL
51	Sour cream	30 mL
52	Yogurt	175 g
	Desserts	
53	Ice cream, ice milk, frozen yogurt and sherbet	125 mL
54	Dairy desserts, frozen, such as cakes, bars, sandwiches or cones	125 mL
55	Non-dairy desserts, frozen, such as flavoured and sweetened ice or pops, or frozen fruit juices in bars or cups	75 mL
56	Sundaes	250 mL
57	Custard, gelatin and pudding	125 mL
	Dessert Toppings and Fillings	
58	Dessert toppings, such as maple butter and marshmallow cream	30 g
59	Cake frostings and icings	35 g
60	Pie fillings	75 mL
	Eggs and Egg Substitutes	
61	Egg mixtures, such as egg foo young, scrambled eggs or omelets	110 g
62	Eggs	50 g
63	Egg substitutes	50 g

Item	Column 1 Food	Column 2 Reference amount[1]
	Fats and Oils	
64	Butter, margarine, shortening and lard	10 g
65	Vegetable oil	10 mL
66	Butter replacement, powder	2 g
67	Dressings for salad	30 mL
68	Mayonnaise, sandwich spread and mayonnaise-type dressing	15 mL
69	Oil, spray type	0.5 g
	Marine and Fresh Water Animals	
70	Canned anchovies, anchovy paste and caviar	15 g[2]
71	Marine and fresh water animals with sauce, such as fish with cream sauce or shrimp with lobster sauce	140 g cooked
72	Marine and fresh water animals without sauce, such as plain or fried fish or shellfish, or fish or shellfish cakes, with or without breading or batter	125 g raw 100 g cooked
73	Marine and fresh water animals, canned	55 g[2]
74	Marine and fresh water animals, smoked or pickled, or spreads	55 g[2]
	Fruit and Fruit Juices	
75	Fruit, fresh, canned or frozen, except those listed as a separate item	140 g 150 mL canned[2]
76	Candied or pickled fruit	30 g[2]
77	Dried fruit, such as raisins, dates or figs	40 g
78	Fruit for garnish or flavour, such as maraschino cherries	4 g[2]
79	Fruit relishes	60 mL
80	Avocado, used as an ingredient	30 g
81	Cranberries, lemons and limes, used as ingredients	55 g
82	Watermelon, cantaloupe, honeydew and other melons	150 g
83	Juices, nectars and fruit drinks represented for use as substitutes for fruit juices	250 mL
84	Juices, used as ingredients, such as lemon juice or lime juice	5 mL

Item	Column 1 Food	Column 2 Reference amount[1]
	Legumes	
85	Bean curd (tofu) and tempeh	85 g[2]
86	Beans, peas and lentils, such as white beans, kidney beans, romano beans, soybeans or chick peas	100 g dry 250 mL cooked or canned[2]
	Meat, Poultry, Their Products and Substitutes[3]	
87	Pork rinds and bacon	54 g uncooked 15 g cooked
88	Beef, pork and poultry breakfast strips	30 g uncooked 15 g cooked
89	Dried meat and poultry, such as jerky, dried beef or parma ham, as well as sausage products with a water activity of 0.90 or less, such as salami, dried thuringer or cervelat	30 g
90	Luncheon meats, such as bologna, blood pudding, minced luncheon roll, liver sausage, mortadella, ham and cheese loaf or headcheese; pâté; sandwich spread; potted meat food product; taco fillings; meat pie fillings and cretons	75 g uncooked 55 g cooked
91	Sausage products, such as linked sausage, Vienna sausage, wieners, breakfast sausage, frankfurters, pork sausage, bratwurst, kielbasa, Polish sausage, summer sausage, smoked sausage, smoked country sausage, pepperoni, knackwurst, thuringer or cervelat	75 g uncooked 55 g cooked
92	Cuts of meat and poultry without sauce, and ready-to-cook cuts, with or without breading or batter, including marinated, tenderized and injected cuts	125 g raw 100 g cooked
93	Patties, cutlettes, chopettes, steakettes, meatballs, sausage meat and ground meat, with or without breading or batter	100 g raw 60 g cooked
94	Cured meat products, such as cured ham, dry cured ham, back bacon, cured pork back, dry cured cappicolo, corned beef, pastrami, country ham, cured pork shoulder picnic, cured poultry ham products, smoked meat or pickled meat	85 g raw 55 g cooked
95	Canned meat and poultry	55 g[2]
96	Meat and poultry with sauce, such as meat in barbecue sauce or turkey with gravy, but excluding combination dishes	140 g

Item	Column 1 Food	Column 2 Reference amount[1]
	Miscellaneous	
97	Baking powder, baking soda and pectin	0.6 g
98	Baking decorations, such as coloured sugars or sprinkles for cookies	4 g
99	Bread crumbs and batter mixes	30 g
100	Cooking wine	30 mL
101	Cocoa powder	5 g
102	Non-alcoholic drink mixers, such as pina colada or daiquiri	250 mL
103	Chewing gum	3 g
104	Salad and potato toppers, such as salad crunchies, salad crispins or substitutes for bacon bits	7 g
105	Salt and salt substitutes, as well as seasoned salt, such as garlic salt	1 g
106	Spices and herbs	0.5 g
	Combination Dishes	
107	Measurable with a cup, such as casserole, hash, macaroni and cheese with or without meat, pot pie, spaghetti with sauce, stir fry, meat or poultry casserole, baked or refried beans, wieners and beans, meat chili, chili with beans, creamed chipped beef, beef or poultry ravioli in sauce, beef stroganoff, poultry à la king, Brunswick stew, goulash, stew, ragout or poutine	250 mL
108	Not measurable with a cup, such as burritos, egg rolls, enchiladas, pizza, pizza rolls, sausage rolls, pastry rolls, cabbage rolls, quiche, sandwiches, crackers and meat or poultry lunch-type packages, gyros, burger on a bun, frank on a bun, calzones, tacos, pockets stuffed with meat, lasagna, chicken cordon bleu, stuffed vegetables with meat or poultry, shish kabobs, empanadas, fajitas, souvlaki, meat pie or tourtière	140 g without gravy or sauce 195 g with gravy or sauce
109	Hors d'oeuvres	50 g
	Nuts and Seeds	
110	Nuts and seeds, not for use as snacks: whole, chopped, sliced, slivered or ground	30 g shelled
111	Butters, pastes and creams, other than peanut butter	30 g
112	Peanut butter	15 g
113	Flours, such as coconut flour	15 g

Item	Column 1 Food	Column 2 Reference amount[1]
	Potatoes, Sweet Potatoes and Yams	
114	French fries, hash browns, skins and pancakes	85 g frozen French fries 70 g prepared
115	Mashed, candied, stuffed or with sauce	140 g
116	Plain, fresh, canned or frozen	110 g fresh or frozen 125 g vacuum packed 160 g canned[2]
	Salads	
117	Salads, such as egg, fish, shellfish, bean, fruit, vegetable, meat, ham or poultry salad, except those listed as a separate item	100 g
118	Gelatin salad	120 g
119	Pasta or potato salad	140 g
	Sauces, Dips, Gravies and Condiments	
120	Sauces for dipping, such as barbecue, hollandaise, tartar, mustard or sweet and sour sauce	30 mL
121	Dips, such as legume or dairy-based	30 g
122	Major main entree sauce, such as spaghetti sauce	125 mL
123	Minor main entree sauce, such as pizza sauce, pesto sauce or other sauces used as toppings, such as white sauce, cheese sauce, salsa, cocktail sauce or gravy	60 mL
124	Major condiments, such as ketchup, steak sauce, soy sauce, vinegar, teriyaki sauce or marinades	15 mL
125	Minor condiments, such as horseradish, hot sauce, mustard or worcestershire sauce	5 mL
	Snacks	
126	Chips, pretzels, popcorn, extruded snacks, grain-based snack mixes and fruit-based snacks, such as fruit chips	50 g
127	Nuts or seeds for use as snacks	50 g shelled
128	Meat or poultry snack food sticks	20 g
	Soups	
129	All varieties	250 mL

Item	Column 1 Food	Column 2 Reference amount[1]
	Sugars and Sweets	
130	Candies, including chocolate bars and other chocolate products, except those listed as a separate item	40 g
131	Hard candies, except those listed as a separate item	15 g
132	Baking candies, such as chocolate chips	15 g
133	Breath mints	2 g
134	Roll-type hard candies and mini size hard candies in dispenser packages	5 g
135	Confectioner's or icing sugar	30 g
136	Bread spreads, except those listed as a separate item, honey and molasses	20 g
137	Jams, jellies, marmalades, fruit butters and spreads	15 mL
138	Marshmallows	30 g
139	Sugars, except those listed as a separate item	4 g
140	Sugar substitute	amount equivalent in sweetness to 4 g of sugar
141	Syrups, including chocolate, maple and corn syrup	30 mL as ingredient 60 mL other uses
	Vegetables	
142	Vegetables without sauce, including cream style corn and stewed tomatoes, but not including vegetables without sauce listed as a separate item	85 g fresh or frozen 125 mL canned[2]
143	Vegetables with sauce	110 g fresh or frozen 125 mL canned
144	Vegetables primarily used for garnish or flavouring, fresh, canned or frozen, but not dried, such as parsley or garlic	4 g
145	Chili pepper and green onion	30 g
146	Seaweed	15 g
147	Lettuce and sprouts	65 g
148	Vegetable juice and vegetable drink	250 mL
149	Olives	15 g[2]
150	Pickles	30 g[2]
151	Relish	15 mL

Item	Column 1 Food	Column 2 Reference amount[1]
152	Vegetable pastes, such as tomato paste	30 mL
153	Vegetable sauce or purée, such as tomato sauce or tomato purée	60 mL

[1]. Unless otherwise noted, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the food. If not listed separately, the reference amount for the unprepared form, such as dry mixes, concentrates, dough, batter, and fresh or frozen pasta, is the amount required to make one reference amount of the prepared form.

[2]. Excludes any liquid in which the solid food may be packed or canned, unless the liquid is customarily consumed with the solid food.

[3]. Meat and poultry substitutes include extended and simulated meat and poultry products.

PART E

CYCLAMATE AND SACCHARIN SWEETENERS

E.01.001. (1) In this Part,

"cyclamate sweetener" means
(a) cyclohexyl sulfamic acid or a salt thereof, or
(b) any substance containing cyclohexyl sulfamic acid or a salt thereof
that is sold as a sweetener;

"saccharin sweetener" means
(a) saccharin or a salt thereof, or
(b) any substance containing saccharin or a salt thereof that is sold as a sweetener.

(2) Part B of these Regulations does not apply to any cyclamate sweetener or saccharin sweetener.

Sale

E.01.002. No person shall

(a) sell a cyclamate sweetener or saccharin sweetener that is not labelled as required by this Part; or
(b) commencing June 15, 1978, sell any saccharin sweetener to the general public except on the premises of a pharmacy.

Advertising

4-5-78 **E.01.003.** No person shall, in advertising to the general public a cyclamate sweetener or saccharin sweetener, make any representation other than with respect to the name, price and quantity of the sweetener.

Labelling

E.01.004. (1) Every cyclamate sweetener that is not also a saccharin sweetener shall be labelled to state that such sweetener should be used only on the advice of a physician.

(2) Commencing June 1, 1979, every saccharin sweetener shall be labelled to state that

(a) continued use of saccharin may be injurious to health; and
(b) it should not be used by pregnant women except on the advice of a physician.

E.01.005. Commencing June 1, 1979, every cyclamate sweetener or saccharin sweetener shall be labelled to show

(a) a list of all the ingredients and, in the case of
(i) cyclohexyl sulfamic acid,
(ii) a salt of cyclohexyl sulfamic acid,
(iii) a saccharin,
(iv) a saccharin salt, or
(v) carbohydrates,
the quantity thereof contained in the sweetener; and

(b) the energy value of the sweetener expressed in calories
(i) per teaspoonful, drop, tablet or other measure used in the directions for use, and
(ii) per 100 grams or 100 millilitres
of the sweetener.

General

14-5-97 **G.01.001.** (1) In this **Part**,

18-6-92 "**agricultural implant**" means a product that is presented in a form suitable to allow sustained release of an active ingredient over a certain period of time and that is intended for insertion under the skin of a food-producing animal for the purpose of increasing weight gain and improving feed efficiency; (*implant agricole*)

"**common name** " with reference to a controlled drug means the name in English or French by which the controlled drug is commonly known;

26-10-04 "**competent authority**" means a public authority of a foreign country that is authorized under the laws of the country to approve the importation or exportation of controlled drugs into or from the country; *(autorité compétente)*

14-5-97 "**controlled drug**" means a drug set out in the schedule to this Part and includes a preparation; (*drogue contrôllée*)

"**hospital**" means a facility

10-1-86 (a) that is licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness, or

(b) that is owned or operated by the Government of Canada or the government of a province and that provides health services; (*hôpital*)

26-10-04 "**international obligation**" means an obligation in respect of a controlled drug set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres; *(obligation internationale)*

26-10-04 Repealed by P.C. 2004-1238 of October 26, 2004.

"**licensed dealer**" means the holder of a licence issued under section G.02.003.2; *(distributeur autorisé)*

"**parenteral use** " with reference to a drug means administration by means of a hypodermic syringe, needle or other instrument through or into the skin or mucous membrane;

"**permit**" means a permit issued under section G.02.008;

"**pharmacist**"

(a) means a person who is registered and entitled under the laws of a province

2-3-78 (i) to practise pharmacy, and

(ii) to operate a pharmacy or dispensary

and who is operating a pharmacy or dispensary and is practising pharmacy thereunder in that province, and

20-11-97 (b) includes, for the purposes of sections G.01.002, G.03.003, G.03.002 to G.03.008, G.03.014, G.03.015 and G.03.017 and subsections G.05.003(3) and (4), a person who is registered and entitled under the laws of a province to practise pharmacy and who is practising pharmacy in that province; (*pharmacien*)

14-5-97 "**practitioner**" is repealed by P.C. 1997-626 of May 14, 1997.

"**preparation**" means a drug that contains a controlled drug and one or more active medicinal ingredients, in a recognized therapeutic dose, other than a controlled drug;

"**prescription**" means a direction given by a practitioner that a stated amount of a specified controlled drug be dispensed for the person named therein;

"**proper name**" with reference to a controlled drug means the name in English or French

(a) assigned to the drug in section C.01.002,

(b) that appears in bold face type for the drug in the Regulations and where the drug is dispensed in a form other than that described in **Part C**, the name of the dispensing form, or

10-4-03 c) assigned in any of the publications mentioned in Schedule B to the *Food and Drugs Act* in the case of a drug not included in paragraph (a) or (b) of this definition; (*nom propre*)

26-10-04 "**qualified person in charge**" means the individual with the qualifications specified in subsection G.02.001.2(2) who is responsible for supervising the activities carried out by a licensed dealer under their licence at the premises specified in the licence; (*personne qualifiée responsable*)

"**test kit**" means an apparatus

(a) that contains reagent systems or buffering agents or both,

14-7-77 (b) that is used in the course of a chemical or analytical procedure for medical, laboratory, industrial, educational or research purposes, and

c) the contents of which are not intended for administration to humans;

"**verbal order**" means an order given orally; (*commande verbale*);

13-6-85 Revoked by P.C. 1985-1939 of June 13, 1985.

(2) The definitions in this subsection apply in this Part and Part J.

10-4-03 "**Act**" means the *Controlled Drugs and Substances Act*; (*Loi*)
14-5-97 "**advertisement**" has the same meaning as in section 2 of the *Food and Drugs Act*. (*publicité* ou *annonce*)
"**Department**" has the same meaning as in section 2 of the *Food and Drugs Act*. (*ministère*)
26-10-04 "**designated criminal offence**" means
(a) an offence involving the financing of terrorism against any of sections 83.02 to 83.04 of the *Criminal Code*;
(b) an offence involving fraud against any of sections 380 to 382 of the *Criminal Code*;
(c) the offence of laundering proceeds of crime against section 462.31 of the *Criminal Code*;
(d) an offence involving a criminal organization against any of sections 467.11 to 467.13 of the *Criminal Code*; or
(e) a conspiracy or an attempt to commit, being an accessory after the fact in relation to, or any counselling in relation to, an offence referred to in paragraphs (a) to (d). (*infraction désignée en matière criminelle*)
"**designated drug offence**" means
(a) an offence against section 39, 44.2, 44.3, 48, 50.2 or 50.3 of the *Food and Drugs Act*, as those provisions read immediately before May 14, 1997,
10-4-03 (b) an offence against section 4, 5, 6, 19.1 or 19.2 of the *Narcotic Control Act*, as those provisions read immediately before May 14, 1997,
(c) an offence under Part I of the *Controlled Drugs and Substances Act*, except subsection 4(1), or
(d) a conspiracy or an attempt to commit, being an accessory after the fact in relation to, or any counselling in relation to, an offence referred to in any of paragraphs (a) to (c); (*infraction désignée en matière de drogue*)
14-5-97 "**label**" has the same meaning as in section 2 of the *Food and Drugs Act*. (*étiquette*)
"**package**" has the same meaning as in section 2 of the *Food and Drugs Act*. (*emballage*)
26-10-04 "**Security Directive**" means the *Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the Storage of Controlled Substances)* published by the Department, as amended from time to time. (*Directive en matière de sécurité*)

(3) Unless otherwise provided, the definitions in subsection 2(1) of the *Controlled Drugs and Substances Act* apply in this Part and Part J.

11-12-03 **G.01.002.** (1) A person is authorized to have a controlled drug set out in any of items 1 to 3, 8 to 10, 12 to 14, 16 or 17 of Part I of the schedule to this Part in his or her possession where the person has obtained the controlled drug under these Regulations, in the course of activities performed in connection with the enforcement or administration of an Act or regulation, or from a person who is exempt under section 56 of the *Controlled Drugs and Substances Act* from the application of subsection 5(1) of that Act with respect to that controlled drug, and the person

(a) requires the controlled drug for his business or profession and is
(i) a licensed dealer,
(ii) a pharmacist, or
(iii) a practitioner who is registered and entitled to practise in the province in which he has such possession;
(b) is a practitioner who is registered and entitled to practise in a province other than the province in which he has such possession and such possession is for emergency medical purposes only;
(c) is a hospital employee or a practitioner in a hospital;
(d) has obtained the controlled drug for his own use from a practitioner or pursuant to a prescription that is not issued or obtained in contravention of these Regulations;
11-3-99 (e) is a practitioner of medicine who received the controlled drug under subsection G.06.001(3) or (4) and whose possession is for a purpose referred to in subsection G.06.001(5);
11-3-99 (f) is an agent of a practitioner of medicine who received the controlled drug under subsection G.06.001(3) and whose possession is for the purpose of complying with subsection G.06.001(4);
(g) is employed as an inspector, a member of the Royal Canadian Mounted Police, a police constable, peace officer or member of the technical or scientific staff of any department of the Government of Canada or of a province or university and such possession is for the purposes of and in connection with such employment;
11-3-99 (h) is a person other than a person referred to in paragraph (e) or (f), is exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to possession of that controlled drug and whose possession is for a purpose set out in the exemption; or
(i) is a person referred to in paragraph G.06.001(5)(b).

(2) A person is authorized to have a controlled drug referred to in subsection (1) in his possession where the person is acting as the agent for any person referred to in paragraph (1)(a) to (e), (h) or (i).

(3) A person is authorized to have a controlled drug referred to in subsection (1) in his possession where

(a) the person is acting as the agent for a person he has reasonable grounds to believe is a person referred to in paragraph(1)(g); and
(b) the possession of the controlled drug is for the purpose of assisting that person in the enforcement or administration of an Act or a regulation.

G.01.002.1 Section C.01.004 does not apply to a test kit that contains a controlled drug where a registration number has been issued for the test kit pursuant to section G.06.002.3 and has not been cancelled pursuant to section G.06.002.4.

10-7-80 **G.01.003.** In the case of a controlled drug that is dispensed by a pharmacist pursuant to a prescription, section C.01.004 does not apply but the label of the package in which controlled drug is contained shall carry the following:

(a) the name and address of the pharmacy or pharmacist;
(b) the date and number of the prescription;
(c) the name of the person for whom the controlled drug is dispensed;
(d) the name of the practitioner;
(e) directions for use; and
(f) any other information that the prescription requires be shown on the label.

14-5-97 **G.01.004.** The *Controlled Drugs and Substances Act* and this Part do not apply in respect of a controlled drug that is contained in an agricultural implant and set out in Part III of the schedule to this Part, but nothing in this section exempts such a drug from the requirements of Part C.

G.01.005. Revoked by P.C. 1980-1849 of July 10, 1980.

28-2-64 **G.01.006.** Except as otherwise provided in this **Part**, no person shall sell a controlled drug or preparation that does not comply with all provisions of **Parts** C and D applicable to it.

G.01.007. No person shall

(a) advertise a controlled drug to the general public; or
28-2-64 (b) issue or publish any other written advertisement respecting a controlled drug unless the advertisement

carries the symbol ◇C◇ in a clear and conspicuous colour and size in the upper left quarter of the first page of the advertisement.

G.01.008. Revoked by P.C. 1980-1849 of July 10, 1980.

Prescribed Manner of Notice of application for an Order of Restoration

14-5-97 **G.01.010.** (1) For the purpose of subsection 24(1) of the *Controlled Drugs and Substances Act*, notice of application for an order of restoration shall be given in writing to the Attorney General by registered mail.

(2) The notice referred to in subsection (1) shall be mailed not less than fifteen clear days prior to the date the application for an order of restoration is to be made to the magistrate and shall specify

5-10-72 (a) the magistrate to whom the application is to be made;
(b) the time and place where the application is to be heard;
(c) the controlled drug or other thing in respect of which the application is to be made; and
(d) the evidence upon which the applicant intends to rely to establish that he is entitled to possession of the controlled drug or other thing referred to in paragraph (c).

Licences and Licensed Dealers

26-10-04 **G.02.001.** Subject to this Part, no person except a licensed dealer shall produce, make, assemble, import, export, sell, provide, transport, send or deliver a controlled drug.

26-10-04 **G.02.001.1.** To be eligible for a dealer's licence, a person must be

(a) an individual who ordinarily resides in Canada;
(b) a corporation that has its head office in Canada or operates a branch office in Canada; or
(c) the holder of a position that includes responsibility for controlled drugs on behalf of a department of the Government of Canada or of a government of a province, a police force, a hospital or a university in Canada.

G.02.001.2. (1) A licensed dealer

(a) shall designate no more than one qualified person in charge, who may be the licensed dealer if the licensed dealer is an individual, who must work at the premises specified in the licence, have responsibility for supervising activities with respect to controlled drugs specified in the licence and for ensuring on behalf of the licensed dealer that those activities comply with these Regulations; and
(b) may designate an alternate qualified person in charge who must work at the premises specified in the licence and have authority to replace the qualified person in charge when that person is absent.

(2) The qualified person in charge and, if applicable, the alternate qualified person in charge

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(a) shall be familiar with the provisions of the Act and the regulations under it that apply to the licence of the licensed dealer who designated them and have knowledge of chemistry and pharmacology and experience in those fields to properly carry out their duties;
(b) shall be a pharmacist or a practitioner registered with a licensing body of a province or possess a degree in an applicable science — such as pharmacy, medicine, dentistry, veterinary medicine, pharmacology, organic chemistry or chemical engineering — that is awarded by a Canadian university or, if awarded by a foreign university, that is recognized by a Canadian university or a Canadian professional association; and
(c) shall not have been convicted, as an adult, within the preceding 10 years, of
  (i) a designated drug offence,
  (ii) a designated criminal offence, or
  (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii).

G.02.002. No licensed dealer may import or export a controlled drug without a permit.

20-11-97 **G.02.002.1** A licensed dealer is authorized to have a controlled drug in his possession for the purpose of exporting the controlled drug from Canada if he has obtained the controlled drug pursuant to these Regulations.

G.02.003. (1) To apply for a dealer's licence, a person shall submit an application to the Minister containing

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(a) if the licence is sought for
  (i) an individual, the individual's name,
  (ii) a corporation, the corporation's name and any other name registered with a province, under which it intends to carry out the activities specified in its dealer's licence or intends to identify itself; and
  (iii) the holder of a position mentioned in paragraph G.02.001.1(c), the applicant's name and the title of the position;
(b) the address, telephone number and, if applicable, the facsimile number and e-mail address for the premises to which the dealer's licence would apply and, if different, the mailing address for the premises;
(c) the name, date of birth and gender of the individual in charge of the premises;
(d) with respect to the qualified person in charge and, if applicable, the alternate qualified person in charge at the premises,
  (i) their name, date of birth and gender,
  (ii) their academic qualifications, training and work experience relevant to their duties,
  (iii) their hours of work at the premises.

(iv) their title at the premises,
(v) the name and title of their immediate supervisor at the premises, and
(vi) in the case of a pharmacist or a practitioner, the name of the province in which the person's current professional licence, certification or authorization was issued and the professional licence, certification or authorization number;

(e) the name and gender of the individuals authorized to place an order for a controlled drug on behalf of the applicant;

(f) in the case of a product or compound that contains a controlled drug but is not a test kit and that would be made or assembled for or by the applicant, a list that sets out
(i) the brand name, if any, of each product or compound,
(ii) the controlled drug in each product or compound,
(iii) the strength per unit of the controlled drug in each product or compound,
(iv) the quantity or package sizes of each product or compound, and
(v) if the product or compound would be made or assembled by or for another licensed dealer under a custom order, the name, address and the dealer's licence number of the other dealer;

(g) the activities referred to in section G.02.001 for which the licence is sought that would be carried out at the premises to which the dealer's licence would apply;

(h) if the licence is sought to produce a controlled drug other than a product or compound that contains a controlled drug,
(i) the name of the controlled drug to be produced,
(ii) the quantity that the applicant expects to produce under the dealer's licence and the period during which that quantity would be produced, and
(iii) if the controlled drug would be produced for another licensed dealer under a custom order, the name, address and dealer's licence number of the other dealer;

(i) a detailed description of the security measures at the premises, determined in accordance with the Security Directive;

(j) a detailed description of the method that the applicant proposes to use for recording their controlled drug transactions; and

(k) for any activity referred to in section G.02.001, other than the activities described in paragraphs (f) and (h), the controlled drug and the purpose for carrying out the activity.

(2) An application for a dealer's licence must

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(a) be signed by the individual in charge of the premises to which the licence would apply; and

(b) be accompanied by a statement signed by the individual in charge indicating that
(i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
(ii) the individual has the authority to bind the applicant.

(3) An application for a dealer's licence must be accompanied by

(a) declarations signed by the individual in charge of the premises, the qualified person in charge and, if applicable, the alternate qualified person in charge, stating that they have not been convicted, as an adult, during the preceding 10 years of
(i) a designated drug offence,
(ii) a designated criminal offence, or
(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(b) a document issued by a Canadian police force with respect to each of the persons referred to in paragraph (a), stating whether the person has or has not been convicted, as an adult, during the preceding 10 years, of a designated drug offence or a designated criminal offence;

(c) if any of the persons referred to in paragraph (a) has ordinarily resided in a country other than Canada during the preceding 10 years, a document issued by a police force of that country stating whether the person has or has not been convicted in that country, as an adult, during the preceding 10 years, of an offence that would have constituted a designated drug offence or a designated criminal offence if committed in Canada;

(d) a statement, signed and dated by the individual in charge of the premises to which the application applies, stating that the qualified person in charge and, if applicable, the alternate qualified person in charge have the knowledge and experience required under paragraph G.02.001.2(2)(a);

(e) if the qualified person in charge or, if applicable, the alternate qualified person in charge is not a pharmacist or a practitioner registered with a licensing body of a province, a copy of the person's degree required under paragraph G.02.001.2(2)(b) and a copy of the course transcript for that degree;

(f) if the applicant's name appears on the label of a product or compound that contains a controlled drug, a copy of the inner label, as defined in section A.01.010, for each product or compound to which the licence would apply; and

(g) if the applicant is a corporation, a copy of
  (i) the certificate of incorporation or other constituting instrument, and
  (ii) any document filed with the province in which the premises to which the licence would apply are located that states its corporate name or any other name registered with the province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself.

(4) The method proposed by the applicant under paragraph (1)(j) must

(a) allow for the recording of controlled drug transactions in accordance with section G.02.014; and
(b) permit the Minister to audit the activities of the licensed dealer with respect to controlled drugs.

(5) The documents referred to in paragraphs (3)(b) and (c) are not required if the persons referred to in those paragraphs consent in writing

(a) to having a criminal record check carried out for them, as an adult, in respect of the offences referred to in those paragraphs during the preceding 10 years;
(b) to provide all necessary information and to submit to any means of identification required to obtain the criminal record check; and
(c) to pay the fee established by the *Royal Canadian Mounted Police, Criminal Record Verification for Civil Purposes Fee Regulations*.

G.02.003.1. The Minister may, on receiving an application made under this Part, require the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to process the application.

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G.02.003.2. Subject to section G.02.003.3, the Minister shall, after examining the information and documents required under sections G.02.003 and G.02.003.1, issue a dealer's licence that contains

(a) the licence number;
(b) the name of the applicant or the title of the position they hold, as the case may be, or, if the applicant is a corporation, its corporate name;
(c) a list of the activities that are permitted;
(d) the address of the premises at which the licensed dealer may carry on the permitted activities;
(e) the name of the controlled drug for which the activities are permitted;
(f) the security level at the premises;
(g) the effective date of the licence;
(h) the expiry date of the licence, which may not be later than three years after its effective date;
(i) any conditions to be met by the holder of the licence to
  (i) ensure that an international obligation is respected,
  (ii) provide the security level referred to in paragraph (f), or
  (iii) reduce the potential security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use;
(j) in the case of a producer of a controlled drug, the quantity of the controlled drug that may be produced under the licence and the period during which that quantity may be produced; and
(k) in the case of the maker or assembler of a product or compound that contains a controlled drug but is not a test kit, an annexed list that sets out the following information for each type of product or compound that may be made or assembled under the licence:
  (i) the licence number,
  (ii) the brand name, if any, of each product or compound,
  (iii) the controlled drug in each product or compound,
  (iv) the strength per unit of the controlled drug in each product or compound, and
  (v) the quantity or package sizes of each product or compound.

G.02.003.3. (1) The Minister shall refuse to issue, renew or amend a dealer's licence if

(a) the applicant is not an eligible person under section G.02.001.1;
(b) an inspector who has requested an inspection has not been given the opportunity by the applicant to conduct an inspection under section G.02.015;
(c) false or misleading information or false or falsified documents were submitted in or with the application;
(d) an activity for which the licence is requested would not be in compliance with an international obligation;
(e) information received from a competent authority or the United Nations raises a reasonable belief that the applicant has been involved in the diversion of a controlled drug to an illicit market or use or has been involved in an activity that was not in compliance with an international obligation;
(f) the applicant does not have in place the security measures set out in the Security Directive in respect of an activity for which the licence is requested;
(g) the applicant is in contravention of or has contravened during the preceding 10 years
    (i) a provision of the Act or the regulations made or continued under it, or
    (ii) a term or condition of another dealer's licence or of an import or export permit issued to the applicant under any regulations made or continued under the Act;
(h) the issuance, amendment or renewal of the licence would likely create a risk to public health, safety or security, including the risk of a controlled drug being diverted to an illicit market or use;
(i) the individual in charge of the premises, the qualified person in charge or, if applicable, the alternate qualified person in charge has been convicted, as an adult, within the previous 10 years, of
    (i) a designated drug offence,
    (ii) a designated criminal offence, or
    (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);
(j) the proposed method referred to in paragraph G.02.003(1)(j) is not capable of recording controlled drug transactions as required under section G.02.014 or permitting the Minister to audit the applicant's activities with respect to controlled drugs in a timely manner; or
(k) the additional information required under section G.02.003.1 has not been provided or is insufficient to process the application.

26-10-04 (2) The Minister is not required to refuse to issue, renew or amend a licence under paragraph (1)(c) or (g) if the applicant

(a) does not have a history of non-compliance with the Act or any regulation made or continued under it; and
(b) has carried out, or signed an undertaking to carry out, specified corrective measures to ensure compliance with the Act and these Regulations.

G.02.003.4. (1) To apply to renew a dealer's licence, a licensed dealer shall submit to the Minister

(a) the information referred to in paragraphs G.02.003(1)(a) to (k); and
(b) the following documents, namely,
    (i) the documents referred to in paragraphs G.02.003(3)(a) and (d) and, subject to subsection G.02.003(5), the document referred to in paragraph G.02.003(3)(b),
    (ii) if applicable and if not previously submitted in respect of the dealer's licence that is being renewed, the document referred to in paragraph G.02.003(3)(e), and
    (iii) the original dealer's licence that is to be renewed.

(2) An application for renewal must

(a) be signed by the individual in charge of the premises to which the renewed dealer's licence would apply; and
(b) be accompanied by a statement signed by the individual in charge indicating that
    (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
    (ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section G.02.003.3, the Minister shall, after examining the information and documents required under subsections (1) and (2) and section G.02.003.1, issue a renewed dealer's licence that contains the information specified in paragraphs G.02.003.2(a) to (k).

G.02.003.5. (1) To have its dealer's licence amended, a licensed dealer shall submit to the Minister

(a) an application in writing describing the proposed amendment, accompanied by the supporting documents referred to in section G.02.003 that are relevant to the proposed amendment; and
(b) the original dealer's licence.

(2) An application for amendment must

(a) be signed by the individual in charge of the premises to which the amended dealer's licence would apply; and
(b) be accompanied by a statement signed by the individual in charge indicating that
  (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
  (ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section G.02.003.3, the Minister shall, after examining the application for amendment and the supporting documentation, amend the dealer's licence in accordance with the application and may add any conditions to be met by the holder of the licence to

(a) ensure that an international obligation is respected;
(b) provide for the security level referred to in paragraph G.02.003.2(f) or the new level required as a result of the amendment being implemented; or
(c) reduce the potential security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use.

G.02.003.6. (1) A licensed dealer shall

(a) obtain the Minister's approval before making any of the following changes, namely,
  (i) a change relating to the security at the premises referred to in the dealer's licence, or
  (ii) the replacement or addition of
    (A) the individual in charge of the premises to which the dealer's licence applies,
    (B) the qualified person in charge and, if applicable, the alternate qualified person in charge at the premises to which the dealer's licence applies, and
    (C) an individual authorized to place an order for a controlled drug on behalf of the licensed dealer;
(b) notify the Minister, not later than 10 days after the change, when a person referred to in clause (a)(ii)(A) or (C) ceases to carry out their duties as specified in
  (i) the application for the dealer's licence under section G.02.003,
  (ii) the application to renew the dealer's licence under section G.02.003.4, or
  (iii) the request for approval under paragraph (a); and
(c) notify the Minister, not later than the next business day after the change, when a person referred to in clause (a)(ii)(B) ceases to carry out their duties as specified in
  (i) the application for the dealer's licence under section G.02.003,
  (ii) the application to renew the dealer's licence under section G.02.003.4, or
  (iii) the request for approval under paragraph (a).

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(2) The licensed dealer shall, with the request for approval referred to in subparagraph (1)(a)(ii), provide the Minister with the following information and documents with respect to the new person:

(a) in the case of the replacement of the individual in charge of the premises to which the dealer's licence applies,
  (i) the information specified in paragraph G.02.003(1)(c), and
  (ii) the declarations specified in paragraph G.02.003(3)(a) and, subject to subsection G.02.003(5), the documents specified in paragraphs G.02.003(3)(b) and (c);
(b) in the case of the replacement of the qualified person in charge or the replacement or addition of the alternate qualified person in charge at the premises to which the dealer's licence applies,
  (i) the information specified in paragraph G.02.003(1)(d), and
  (ii) the documents specified in paragraphs G.02.003(3)(a), (d) and (e) and, subject to section G.02.003(5), the documents specified in paragraphs G.02.003(3)(b) and (c); and
(c) in the case of the replacement or addition of an individual who is authorized to place an order for a controlled drug on behalf of the licensed dealer, the individual's name and gender.

G.02.003.7. The Minister shall revoke a dealer's licence at the request of the licensed dealer or on being notified by the licensed dealer that the licence has been lost or stolen.

G.02.003.8. (1) Subject to subsection (2), the Minister shall revoke a dealer's licence in accordance with section G.02.003.91 if

(a) the licence was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application;
(b) the licensed dealer has failed to comply with a provision of the Act, a regulation under it or a term or condition of the licence or of an import or export permit issued under this Part;
(c) the licensed dealer is no longer an eligible person under section G.02.001.1;
(d) it is discovered that the individual in charge of the premises to which the licence applies, the qualified person in charge or, if applicable, the alternate qualified person in charge at those premises, has been convicted, as an adult, within the preceding 10 years, of
    (i) a designated drug offence,
    (ii) a designated criminal offence, or
    (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii); or
(e) information received from a competent authority or the United Nations raises a reasonable belief that the licensed dealer has been involved in the diversion of a controlled drug to an illicit market or use.

(2) The Minister is not required to revoke a dealer's licence under paragraph (1)(a) or (b) if the licensed dealer

(a) has no history of non-compliance with the Act and the regulations made or continued under it; and
(b) has carried out, or signed an undertaking to carry out, corrective measures to ensure compliance with the Act and these Regulations.

26-10-04 **G.02.003.9.** The Minister shall suspend a dealer's licence without prior notice if it is necessary to do so to protect security, public health or safety, including preventing a controlled drug from being diverted to an illicit market or use.

G.02.003.91. (1) If the Minister proposes to refuse to issue, amend or renew, or proposes to revoke, a dealer's licence under this Part, the Minister shall

(a) send a notice to the applicant or to the holder of the licence, together with a written report that sets out the reasons for the proposed refusal or revocation; and
(b) give the applicant or holder an opportunity to be heard in respect of the proposed refusal or revocation.

(2) The suspension of a dealer's licence under this Part takes effect as soon as the Minister notifies the holder of the licence of the decision to suspend and provides a written report that sets out the reasons for the suspension.

(3) A person who receives a notice of suspension referred to in subsection (2) may, within 10 days after receiving the notice, provide the Minister with reasons why the suspension of the licence is unfounded.

G.02.004. A licensed dealer may, subject to the terms and conditions of their licence, produce, make, assemble, sell, provide, transport, send or deliver only the controlled drugs specified in their dealer's licence.

G.02.008. The Minister may, upon application therefor, issue a permit to any licensed dealer for the importation or exportation of a controlled drug.

28-2-64 **G.02.009.** An application for a person shall be in a form approved by the Minister.

G.02.010. Every licence or permit issued under this **Part** is subject to the condition that the licensed dealer will comply with the provisions of this **Part**.

26-10-04 **G.02.011.** The Minister shall revoke or suspend a permit issued under this Part if the Minister determines that the person to whom the permit was issued has failed to comply with any term or condition of the permit or any provision of these Regulations.

26-10-04 **G.02.012.** A dealer's licence is valid until the earlier of

(a) the expiry date set out in the licence, and
(b) the revocation or suspension of the licence under section G.02.003.7, G.02.003.8 or G.02.003.9.

G.02.013. A permit issued under section G.01.008 is valid only for the particular importation or exportation in respect of which it was issued.

G.02.014. (1) Every licensed dealer shall keep a record of the following:

(a) the name and quantity of any controlled drug received by the licensed dealer, the name and address of the person who sold or provided it and the date it was received;
26-10-04 (b) the name, quantity and form of any controlled drug sold or provided by the licensed dealer, the name and address of the person to whom it was sold or provided and the date it was sold or provided;
(c) the name and quantity of any controlled drug used in the making or assembling of a product or compound containing that narcotic, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;
(c.1) the name and quantity of any narcotic produced and the date on which it was placed in stock; and
(d) the name and quantity of any controlled drug he had in stock at the end of each month.

(2) The record of information referred to in subsection (1) shall be kept

(a) in a manner that permits an audit to be made;
4-5-78 (b) subject to subsection (3), in a book, register or similar record maintained exclusively for controlled drugs; and
(c) for any period of at least two years on the premises described in the licence of the licensed dealer.

14-5-97 (3) The record of information referred to in paragraphs (1) *(a)*, *(b)* and *(d)* may, with respect to a controlled drug listed in Part II or III of the schedule to this Part, be kept in a form other than that specified in paragraph (2)*(b)*.

G.02.015. (1) The Minister may, in respect of an applicant for a dealer's licence or a licensed dealer, require an inspection, at any reasonable time, of

(a) the premises used or intended to be used in producing, making, assembling or storing a controlled drug; and
26-10-04 (b) the process and conditions of the producing, making, assembling or storing.

(2) The Minister may, in respect of a licensed dealer, require a verification to be made, at any reasonable time, of the qualifications of its technical staff concerned with producing, making, assembling or storing a controlled drug.

G.02.016. Every licensed dealer shall

(a) furnish such information respecting the dealings of such person in any controlled drug in such form and at such times as the Minister may require;
(b) produce to an inspector any books, records or documents required to be kept by this **Part**;
(c) permit an inspector to make copies of or to take extracts from such books, records and documents; and
(d) permit an inspector to check all stock of controlled drugs located on the premises described in the licence of the licensed dealer.

4-5-78 **G.02.017.** Revoked by P.C. 1978-1520 of May 4, 1978.

G.02.018. Every licensed dealer shall notify the Minister promptly of changes in the following:

(a) his technical staff;
26-10-04 (b) the premises in which a controlled drug is produced, made, assembled or stored; and
(c) the process and conditions of the producing, making, assembling or storing.

G.02.019. Every licensed dealer shall

28-2-64 (a) provide such protection against loss or theft of any controlled drug in his possession as may be required by the Minister;
(b) report to the Minister any loss or theft of a controlled drug within ten days of his discovery thereof; and
(c) securely pack a controlled drug in its immediate container and seal it in such a manner that it cannot be opened without breaking the seal.

G.02.020. A licensed dealer may only import into or export out of Canada a controlled drug at the place specified in his permit.

G.02.021. A licensed dealer shall securely pack in a package sealed in such a manner that it cannot be opened without breaking the seal any controlled drug intended for export out of Canada.

G.02.022. A licensed dealer shall in taking delivery of a controlled drug imported by him or in making delivery of a controlled drug
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(a) take such steps as are necessary to ensure the safekeeping of the drug during transit; and
(b) use such method of transportation as will ensure an accurate record being kept of the drug and of the signatures of any persons having charge of the drug until it is delivered to the consignee.

28-2-64 **G.02.023.** Notwithstanding section G.02.022, a preparation may be delivered by common carrier.

26-10-04 **G.02.024.** A licensed dealer shall not sell or provide a controlled drug to any person other than a

(a) licensed dealer;
(b) pharmacist;
(c) practitioner;
13-6-85 (d) hospital employee or a practitioner in a hospital;
26-10-04 (e) Regional Director of the Department; or
11-3-99 (f) person who has been granted an exemption under section 56 of the *Controlled Drugs and Substances Act* with respect to the possession of a controlled drug.

26-5-77 **G.02.024.1** Subject to section G.02.024.2 and notwithstanding sections G.02.024 and G.02.025, no licensed dealer shall

26-10-04 (a) sell or provide a controlled drug, other than a preparation, to a pharmacist named in a notice given by the Minister under section G.03.017.2;
(b) sell or provide a preparation to a pharmacist named in a notice given by the Minister under section G.03.017.2;
(c) sell or provide a controlled drug, other than a preparation, to a practitioner named in a notice given by the Minister under section G.04.004.2; or
(d) sell or provide a preparation to a practitioner named in a notice given by the Minister under section G.04.004.2.

G.02.024.2 Section G.02.024.1 does not apply to a licensed dealer to whom the Minister has issued a notice of retraction of the notice

10-4-03 (a) under section G.03.017.3, in respect of a pharmacist named in a notice issued by the Minister under section G.03.017.2; or
(b) under section G.04.004.3, in respect of a practitioner named in a notice issued by the Minister under section G.04.004.2.

G.02.025. (1) Subject to this section, a licensed dealer may, in accordance with the terms and conditions of their dealer's licence, sell or provide a controlled drug to a person referred to in section G.02.024 if

26-10-04 (a) the drug is contained in a package that is authorized and described in the dealer's licence of the producer, maker or assembler of the drug; and
4-5-78 (b) the licensed dealer has received, on the premises described in the licence,
(i) a written order,
(ii) an order sent through a computer from a remote input device, or
14-5-97 (iii) a verbal order for a controlled drug listed in Part II or III of the schedule to this Part.

(2) A licensed dealer who has received an order referred to in subparagraph (1)(b)(i) and verified the signature on the order may sell or provide a controlled drug to a person referred to in section G.02.024, if the order is signed and dated by one of the following persons:

26-10-04 (a) if the controlled drug is to be sold or provided to a person referred to in paragraph G.02.024(2)(a), (b), (c), (e) or (f), by that person; or
(b) if the controlled drug is to be provided to a hospital employee or a practitioner in a hospital, by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to sign the order.

(3) A licensed dealer may sell or provide a controlled drug pursuant to an order received from a remote input device through a computer if the computer program and the remote input device meet the requirements of subsections (5) and (6).

(3.1) A licensed dealer who has received an order sent through a computer from a remote input device referred to in subparagraph (1)(b)(ii) may provide a controlled drug to a hospital employee or to a practitioner in a hospital if the order has been placed by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to place the order.

(3.2) A licensed dealer who has received a verbal order referred to in subparagraph (1)(b)(iii) may provide a controlled drug listed in Part II or III of the schedule to this Part to a hospital employee or to a practitioner in a hospital if the order has been placed by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to place the order.

(4) A licensed dealer who has received a verbal order referred to in subparagraph (1)(b)(iii), and has provided a controlled drug listed in Part II or III of the schedule to this Part to a person referred to in paragraphs G.02.024(b) to (d), shall immediately record

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(a) the name of the person to whom the controlled drug was sold or provided;
(b) if the drug was provided to a hospital employee or a practitioner in a hospital, the name of the pharmacist in charge of the dispensary of the hospital or the name of the practitioner authorized by the person in charge of the hospital to sign the order; and
13-6-85 (c) the date that the order is received.

(5) For the purposes of this section, a remote input device shall be a device for transmitting electronically orders for drugs, other than by voice communication, that

(a) contains a unique identifying code that can be related to the device and the pharmacist or practitioner in whose possession and care the remote input device has been placed;
2-3-78 (b) is in the possession and care of that pharmacist or practitioner; and
(c) is designed in such a way that the unique identifying code for the remote input device is an integral part of the circuitry and can only be modified by the dismantling of the device.

(6) For the purposes of this section, a computer program shall be able to

(a) identify the remote input device, the name and address of the pharmacist or practitioner in whose possession and care the remote input device has been placed;
(b) identify the pharmacist or practitioner placing the order by means of an identifying code unique to that pharmacist or practitioner;
(c) process separately and identify controlled drugs by the segregation of the orders for those drugs;
(d) detect unusual orders and thereby necessitate manual intervention by the licensed dealer; and
(e) necessitate manual intervention by the licensed dealer if one or more of the check procedures fails.

13-6-85 (7) Where a licensed dealer has received, from a pharmacist or practitioner, an order sent through a computer from a remote input device referred to in subparagraph (1)(b)(ii) or a verbal order referred to in subparagraph (1)(b)(iii), he shall, within 5 working days of filling the order for a controlled drug, obtain and keep a receipt that includes

(a) the signature of the pharmacist or the practitioner who received the controlled drug;
2-3-78 (b) the date the pharmacist or practitioner received the controlled drug; and
(c) the name and the quantity of the controlled drug.

26-10-04 (8) If a licensed dealer has not received a receipt from a pharmacist or practitioner under subsection (7) within the time prescribed by that subsection, the dealer shall not, until after receiving the receipt, sell or provide a controlled drug to the pharmacist or practitioner pursuant to a further

26-10-04 (a) order sent through a computer from a remote input device referred to in subparagraph (1)(b)(ii); or
(b) verbal order referred to in subparagraph (1)(b)(iii).

26-10-04 **G.02.026.** A licensed dealer shall not sell or provide a controlled drug more than once in respect of one order unless

(a) the order for the drug states that the quantity of the drug is to be sold or provided
(i) in specified portions,
28-2-66 (ii) in separate deliveries not exceeding four deliveries, and
(iii) at specified intervals; or
26-10-04 (b) at the time of receipt of the order the licensed dealer temporarily does not have in stock the quantity of the drug ordered, in which case the dealer may sell or provide against the order the quantity of the drug that the dealer has available and deliver the balance later in accordance with the order.

G.02.027. Revoked by P.C. 1980-1849 of July 10, 1980.

Pharmacists

26-10-04 **G.03.001.** (1) A pharmacist, on receipt of a controlled drug from a licensed dealer, shall keep a record of the name and quantitiy of the controlled drug received by them, the name and address of the person who sold or provided it and the date it was received.

(2) The record of information referred to in subsection (1) shall be kept

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(a) in a manner that permits an audit to be made; and
(b) subject to subsection (3), in a book, register or similar record maintained exclusively for controlled drugs.

14-5-97 (3) The record of information referred to in subsection (1) may, with respect to a controlled drug listed in Part II or III of the schedule to this Part, be kept in a form other than that specified in paragraph (2)(b).

26-10-04 **G.03.002.** No pharmacist shall, except as otherwise provided in this Part, sell or provide a controlled drug to any person unless the pharmacist has first been provided with a prescription for it, and

(a) if the prescription is in writing, it has been signed and dated by the practitioner issuing the same and the signature of the practitioner where not known to the pharmacist, has been verified by him; or
(b) if the prescription is given verbally, the pharmacist has taken reasonable precaution to satisfy himself that the person giving the prescription is a practitioner.

G.03.002.1 Subject to section G.03.002.2 and notwithstanding sections G.03.002, G.03.003 and G.03.005, no pharmacist shall

(a) sell or provide a controlled drug, other than a preparation, to a pharmacist named in a notice given by the Minister under section G.03.017.2;
26-10-04 (b) sell or provide a preparation to a pharmacist named in a notice given by the Minister under section G.03.017.2;
(c) dispense, sell or provide a controlled drug, other than a preparation, to, or pursuant to a prescription or order given by, a practitioner named in a notice given by the Minister under section G.04.004.2; or
(d) dispense, sell or provide a preparation to a practitioner or pursuant to a prescription or order given by a practitioner named in a notice given by the Minister under section G.04.004.2.

G.03.002.2 Section G.03.002.1 does not apply to a pharmacist to whom the Minister has issued a notice of retraction of the notice

10-4-03 (a) under section G.03.017.3, in respect of a pharmacist named in a notice issued by the Minister under section G.03.017.2; or
(b) under section G.04.004.3, in respect of a practitioner named in a notice issued by the Minister under section G.04.004.2.

26-10-04 **G.03.003.** A pharmacist may sell or provide a controlled drug to a practitioner for use in their practice

13-6-85 (a) upon a written order, signed and dated by that practitioner, that has been verified if the signature of the practitioner is unknown to the pharmacist; or
26-10-04 (b) upon a verbal order specifying the name and quantity of the drug if the pharmacist has taken reasonable precautions to satisfy themself that the person making the order is a practitioner.

26-10-04 **G.03.004.** A pharmacist shall, in respect of controlled drugs sold or provided to a practitioner under section G.03.003, keep in a special prescription file a record showing the date, the name and address of the practitioner, and the quantity and kind of controlled drug sold or provided.

26-10-04 **G.03.005.** A pharmacist may provide a controlled drug to a hospital employee or to a practitioner in a hospital on receipt of a written order signed and dated by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to sign the order, if the signature of that pharmacist or practitioner is known to the pharmacist or, if unknown, has been verified.

28-2-64 **G.03.006.** A pharmacist shall not refill a prescription for a controlled drug unless

14-5-97 (a) the practitioner, at the time that he issued the prescription, directed in writing, in the case of a controlled drug listed in Part I of the schedule to this Part, or directed in writing or orally, in the case of a controlled drug listed in Part II or III of the schedule to this Part, that the prescription be refilled, the number of times that it may be refilled and the dates for or the intervals between refills; and

4-5-78 (b) the pharmacist keeps a record of each refilling of a prescription.

14-5-97 **G.03.007.** A pharmacist who dispenses, pursuant to an order or prescription, a controlled drug listed in Part I of the schedule to this Part, other than a preparation, shall forthwith enter in a book, register or similar record maintained for such purposes

(a) the name and address of the person named in the order or prescription;

4-5-78 (b) the name, initials and address of the practitioner who issued the order or prescription;

(c) the name or initials of the pharmacist who dispensed the controlled drug;

(d) the name, quantity and form of the controlled drug dispensed;

26-10-04 (e) the date on which the controlled drug was sold or provided; and

(f) the number assigned to the order or prescription.

13-6-85 **G.03.008.** A pharmacist shall, before dispensing a controlled drug pursuant to a prescription given orally or a verbal order, make a written record thereof, setting forth,

(a) the name and address of the person named in the prescription;

(b) the name, quantity and form of such controlled drug;

(c) the directions for use given therewith;

(d) the name, initials and address of the practitioner who issued the prescription;

(e) the name or initials of the pharmacist who dispensed such controlled drug;

26-10-04 (f) the date on which the controlled drug was sold or provided; and

(g) the number assigned to the prescription.

G.03.009. A pharmacist shall maintain a special prescription file in which shall be filed in sequence as to date and number all written orders or prescriptions in writing for controlled drugs dispensed and the written record of all controlled drugs dispensed pursuant to a prescription or order verbally given.

G.03.010. A pharmacist shall retain in his possession for a period of at least two years, any records which he is required to keep by this **Part**.

G.03.011. A pharmacist shall

(a) furnish such information respecting the dealings of the pharmacist in any controlled drug in such form and at such times as the Minister may require;

(b) make available and produce to an inspector upon request his special prescription file together with any books, records or documents which he is required to keep;

(c) permit an inspector to make copies of or to take extracts from such files, books, records or documents; and

(d) permit an inspector to check all stocks of controlled drugs on his premises.

13-6-85 **G.03.012.** A pharmacist shall take all reasonable steps that are necessary to protect controlled drugs on his premises or under his control against loss or theft.

G.03.013. A pharmacist shall report to the Minister any loss or theft of a controlled drug within ten days of his discovery thereof.

13-6-85 **G.03.014.** A pharmacist may, upon receiving a written order for a controlled drug signed and dated by

(a) the licensed dealer who sold or provided that drug to them, return that drug to that dealer;
(b) another pharmacist, sell or provide any quantity of that drug to that other pharmacist that is specified in the order as being required for emergency purposes;
26-10-04 (c) a Regional Director of the Department, sell or provide to or in accordance with the order of that Director any quantity of that drug, specified in the order, that is required by the Director in connection with their duties; and
(d) a person exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to that controlled drug, sell or provide to that person any quantity of that drug that is specified in the order.

26-10-04 **G.03.015.** A pharmacist shall immediately after receiving, selling or providing a controlled drug under paragraph G.03.014(b) or (c) or subsection G.05.003(4) enter the details of the transaction in a book, register or other record maintained for the purpose of recording such transactions.

28-2-64 **G.03.016.** A pharmacist shall forthwith after removing, transporting or transferring a controlled drug from his place of business to any other place of business operated by him notify the Minister, setting out the details.

G.03.017. The Minister shall provide in writing any factual information about a pharmacist that has been obtained under the Act or these Regulations to the licensing authority responsible for the registration or authorization of the person to practise their profession

(a) in the province in which the pharmacist is registered or entitled to practise if
  (i) the authority submits a written request that states the name and address of the pharmacist, a description of the information being sought and a statement that the information is required for the purpose of assisting a lawful investigation by the authority, or
  (ii) the Minister has reasonable grounds to believe that the pharmacist has
    (A) contravened a rule of conduct established by the authority,
    (B) been found guilty in a court of law of a designated drug offence or of a contravention of this Part, or
    (C) contravened a provision of this Part; or
10-4-03 (b) in a province in which the pharmacist is not registered or entitled to practise, if the authority submits to the Minister
  (i) a written request for information that states
    (A) the name and address of the pharmacist, and
    (B) a description of the information being sought, and
  (ii) documentation that shows that the pharmacist has applied to that authority to practise in that province.

G.03.017.1. A pharmacist may make a written request to the Minister to send to the persons and authorities specified in subsection G.03.017.2(3) a notice, issued under section G.03.017.2, advising them that recipients of the notice must not sell or provide a controlled drug other than a preparation, a preparation, or both, to that pharmacist.

G.03.017.2. (1) In the circumstances described in subsection (2), the Minister must issue a notice to the persons and authorities specified in subsection (3) advising them that licensed dealers and pharmacists practising in the notified pharmacies must not sell or provide to the pharmacist named in the notice a controlled drug other than a preparation, a preparation, or both.

(2) The notice must be issued if the pharmacist named in the notice has

(a) made a request to the Minister in accordance with section G.03.017.1 to issue the notice;
(b) contravened a rule of conduct established by the licensing authority of the province in which the pharmacist is practising and that licensing authority has requested the Minister in writing to issue the notice; or
(c) been found guilty in a court of law of a designated drug offence or of an offence under this Part.

(3) The notice must be issued to

(a) all licensed dealers;
(b) all pharmacies within the province in which the pharmacist named in the notice is registered and practising;
(c) the licensing authority of the province in which the pharmacist named in the notice is registered or entitled to practise; and
(d) any interested licensing authority in another province that has made a request to the Minister to issue the notice.

(4) Subject to subsection (5), the Minister may issue the notice described in subsection (1) to the persons and authorities specified in subsection (3), if the Minister, on reasonable grounds, believes that the pharmacist named in the notice

(a) has contravened any of the provisions of sections G.03.001 to G.03.016;
(b) has, on more than one occasion, self-administered a controlled drug, other than a preparation, contrary to accepted pharmaceutical practice;
(c) has, on more than one occasion, self-administered a preparation, contrary to accepted pharmaceutical practice;
(d) has, on more than one occasion, provided or administered a controlled drug, other than a preparation, to a person who is a spouse, common-law partner, parent or child of the pharmacist, including a child adopted in fact, contrary to accepted pharmaceutical practice;
10-4-03 (e) has, on more than one occasion, provided or administered a preparation to a person who is a spouse, common-law partner, parent or child of the pharmacist, including a child adopted in fact, contrary to accepted pharmaceutical practice; or
(f) is unable to account for the quantity of controlled drug for which the pharmacist was responsible under this Part.

(5) In the circumstances described in subsection (4), the Minister must not issue the notice referred to in subsection (1) until the Minister has

(a) consulted with the licensing authority of the province in which the pharmacist to whom the notice relates is registered or entitled to practise;
(b) given that pharmacist an opportunity to present reasons why the notice should not be issued and considered those reasons; and
(c) considered
  (i) the compliance history of the pharmacist in respect of the Act and the regulations made or continued under it, and
  (ii) whether the actions of the pharmacist pose a significant security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use.

G.03.017.3. The Minister must provide the licensed dealers, pharmacies and licensing authorities who were issued a notice under subsection G.03.017.2(1) with a retraction of that notice if

(a) in the circumstance described in paragraph G.03.017.2(2)(a), the requirements set out in subparagraphs (b)(i) and (ii) have been met and one year has elapsed since the notice was issued by the Minister; or
(b) in a circumstance described in any of paragraphs G.03.017.2(2)(b) and (c) and (4)(a) to (f), the pharmacist named in the notice has
  (i) requested in writing that a retraction of the notice be issued, and
  (ii) provided a letter from the licensing authority of the province, in which the pharmacist is registered or entitled to practise, in which the authority consents to the retraction of the notice.

Practitioners

G.04.001. (1) In this section

26-10-04 (a) "**administer**" includes to prescribe, sell or provide; (*administrer*)
(b) "**designated drug**" means any of the following controlled drugs;
(i) amphetamine and its salts;
(ii) benzphetamine and its salts;
(iii) methamphetamine and its salts;
(iv) phenmatrazine and its salts; or
(v) phendimetrazine and its salts.

11-3-99 (2) Subject to subsections (3) and (4) and to an exemption granted under section 56 of the *Controlled Drugs and Substances Act* with respect to the administration of the controlled drug specified in the exemption, no practitioner shall administer a controlled drug to any person or animal.

(3) A practitioner may administer a controlled drug, other than a designated drug, to a person or to an animal, if
(a) that person or animal is a patient under his professional treatment; and
(b) the controlled drug is required for the condition for which the patient is receiving treatment.

11-12-73 (4) A practitioner may administer a designated drug to an animal or a person who is a patient under his professional treatment where the designated drug is for the treatment of any of the following conditions;

(a) in humans
(i) narcolepsy,
(ii) hyperkinetic disorders in children,
(iii) mental retardation (minimal brain dysfunction),
19-12-72 (iv) epilepsy,
(v) parkinsonism, or
(vi) hypotensive states associated with anaesthesia; or

(b) in animals, depression of cardiac and respiratory centres.

G.04.002. (1) A practitioner who sells or provides a controlled drug to a person for self-administration or for administration to an animal shall, whether or not the practitioner charges for the drug, keep a record showing the name and quantity of the controlled drug sold or provided, the name and address of the person to whom it was sold or provided and the date on which it was sold or provided if the quantity of the controlled drug exceeds

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(a) three times the maximum daily dosage recommended by the producer, maker or assembler of the controlled drug; or
(b) three times the generally recognized maximum daily therapeutic dosage for that controlled drug if the producer, maker or assembler has not recommended a maximum daily dosage.

(2) A practitioner who is required by this section to keep a record shall keep the record in a place, form and manner that will permit an inspector readily to examine and obtain information from it.

G.04.002A. A practitioner shall

(a) furnish to the Minister on request such information respecting
26-10-04 (i) the use by the practitioner of controlled drugs received — including the administering, selling or providing of the drugs to a person — , and
(ii) the prescriptions for controlled drugs issued by the practitioner, as the Minister may require;
(b) produce to an inspector on request any records that these Regulations require the practitioner to keep;
13-5-66 (c) permit an inspector to make copies of such records or to take extracts therefrom;
(d) permit an inspector to check all stocks of controlled drugs on the practitioner's premises;
(e) retain in his possession for at least two years any record that these Regulations require him to keep;

(f) take adequate steps to protect controlled drugs in his possession from loss or theft; and
(g) report to the Minister any loss or theft of a controlled drug within ten days of the practitioner's discovery of the loss or theft.

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G.04.003. If a practitioner alleges or, in any prosecution for an offence under the Act, the *Food and Drugs Act* or this Part, pleads that their possession of a controlled drug was for use in their practice or that they administered it to a person or animal, or prescribed, sold or provided it for a person or an animal who or that was a patient under their professional treatment and that the controlled drug was required for the condition for which the patient received treatment, the burden of proof in respect of the allegation or plea shall be on the practitioner.

G.04.004. The Minister shall provide in writing any factual information about a practitioner that has been obtained under the Act or these Regulations to the licensing authority responsible for the registration or authorization of the person to practise their profession

(a) in the province in which the practitioner is registered or entitled to practise if
  (i) the authority submits a written request that states the name and address of the practitioner, a description of the information being sought and a statement that the information is required for the purpose of assisting a lawful investigation by the authority, or
  (ii) the Minister has reasonable grounds to believe that the practitioner has
    (A) contravened a rule of conduct established by the authority,
    (B) been found guilty in a court of law of a designated drug offence or of a contravention of this Part, or
    (C) contravened a provision of this Part; or

(b) in a province in which the practitioner is not registered or entitled to practise, if the authority submits to the Minister
  (i) a written request for information that states
    (A) the name and address of the practitioner, and
    (B) a description of the information being sought, and
  (ii) documentation that shows that the practitioner has applied to that authority to practise in that province.

10-4-03

G.04.004.1. A practitioner may make a written request to the Minister to send to licensed dealers and pharmacies a notice, issued under section G.04.004.2, advising them of one or more of the following requirements:

(a) recipients of the notice must not sell or provide a controlled drug, other than a preparation, to that practitioner;
(b) recipients of the notice must not sell or provide a preparation to that practitioner;
(c) pharmacists practising in the notified pharmacies must not fill a prescription or order for a controlled drug, other than a preparation, from that practitioner; and
(d) pharmacists practising in the notified pharmacies must not fill a prescription or order for a preparation from that practitioner.

G.04.004.2. (1) In the circumstances described in subsection (2), the Minister must issue a notice to the persons and authorities specified in subsection (3) advising them that

(a) licensed dealers and pharmacists practising in the notified pharmacies must not sell or provide to the practitioner named in the notice a controlled drug other than a preparation, a preparation, or both; or
(b) pharmacists practising in the notified pharmacies must not fill a prescription or order from the practitioner named in the notice for a controlled drug other than a preparation, a preparation, or both.

(2) The notice must be issued if the practitioner named in the notice has

(a) made a request to the Minister in accordance with section G.04.004.1 to issue the notice;
(b) contravened a rule of conduct established by the licensing authority of the province in which the practitioner is practising and that licensing authority has requested the Minister in writing to issue the notice; or
(c) been found guilty in a court of law of a designated drug offence or of an offence under this Part.

(3) The notice must be issued to

(a) all licensed dealers;
(b) all pharmacies within the province in which the practitioner named in the notice is registered and practising;
(c) the licensing authority of the province in which the practitioner named in the notice is registered or entitled to practise;
(d) any interested licensing authority in another province that has made a request to the Minister to issue the notice; and
(e) all pharmacies in an adjacent province in which a prescription or order from the practitioner named in the notice may be filled.

(4) Subject to subsection (5), the Minister may issue the notice described in subsection (1) to the persons and authorities specified in subsection (3), if the Minister, on reasonable grounds, believes that the practitioner named in the notice

(a) has contravened any of the provisions of sections G.04.001 to G.04.002A;
(b) has, on more than one occasion, self-administered a controlled drug, other than a preparation, under a self-directed prescription or order or, in the absence of a prescription or order, contrary to accepted medical, dental or veterinary practice;
(c) has, on more than one occasion, self-administered a preparation, under a self-directed prescription or order or, in the absence of a prescription or order, contrary to accepted medical, dental or veterinary practice;
10-4-03 (d) has, on more than one occasion, prescribed, provided or administered a controlled drug, other than a preparation, to a person who is a spouse, common-law partner, parent or child of the practitioner, including a child adopted in fact, contrary to accepted medical, dental or veterinary practice;
(e) has, on more than one occasion, prescribed, provided or administered a preparation to a person who is a spouse, common-law partner, parent or child of the practitioner, including a child adopted in fact, contrary to accepted medical, dental or veterinary practice; or
(f) is unable to account for the quantity of controlled drug for which the practitioner was responsible under this Part.

(5) In the circumstances described in subsection (4), the Minister must not issue the notice referred to in subsection (1) until the Minister has

(a) consulted with the licensing authority of the province in which the practitioner to whom the notice relates is registered or entitled to practise;
(b) given that practitioner an opportunity to present reasons why the notice should not be issued and considered those reasons; and
(c) considered
  (i) the compliance history of the practitioner in respect of the Act and the regulations made or continued under it, and
  (ii) whether the actions of the practitioner pose a significant security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use.

G.04.004.3. The Minister must provide the licensed dealers, pharmacies and licensing authorities who were issued a notice under subsection G.04.004.2(1) with a notice of retraction of that notice if

(a) in the circumstance described in paragraph G.04.004.2(2)(a), the requirements set out in subparagraphs (b)(i) and (ii) have been met and one year has elapsed since the notice was issued by the Minister; or
(b) in a circumstance described in any of paragraphs G.04.004.2(2)(b) and (c) and (4)(a) to (f), the practitioner named in the notice has
  (i) requested in writing that a retraction of the notice be issued, and
  (ii) provided a letter from the licensing authority of the province, in which the practitioner is registered or entitled to practise, in which the authority consents to the retraction of the notice.

Hospitals

G.05.001. (1) A person who is in charge of a hospital shall keep or cause to be kept a record of the following information:

13-6-85 (a) the name and quantity of any controlled drug received for the hospital by a hospital employee or a practitioner in the hospital;

(b) the name and address of the person from whom any controlled drug was received and the date on which it was received;

26-10-04 (c) the name and quantity of any controlled drug used in the making or assembling of a product or compound containing that controlled drug, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;

(c.1) the name and quantity of any controlled drug produced and the date on which it was placed in stock;

(d) the name of the patient for whom a controlled drug was dispensed;

(e) the name of the practitioner ordering or prescribing a controlled drug; and

4-5-78 (f) the date on which a controlled drug was ordered or prescribed and the form and quantity thereof.

(2) Subject to subsections (3) and (4), the record of information referred to in subsection (1) shall be kept

(a) in a manner that permits an audit to be made;

(b) in a book, register or similar record maintained exclusively for controlled drugs; and

(c) for a period of at least two years.

15-9-88 (3) The information referred to in paragraphs (1)(d) to (f) may, with respect to a preparation, be kept in a form other than that specified in paragraph (2)(b).

14-5-97 (4) The information referred to in subsection (1) may, with respect to a controlled drug listed in Part II or III of the schedule to this Part, be kept in a form other than that specified in paragraph (2)(b).

G.05.002. A person who is in charge of a hospital shall

(a) furnish such information respecting the use of controlled drugs therein, in such form and at such times as the Minister may require;

(b) produce to an inspector any books, records or documents required by these Regulations to be kept;

(c) permit an inspector to make copies thereof or take extracts from such books, records and documents; and

(d) permit an inspector to check all stocks of controlled drugs in the hospital.

G.05.003. (1) No person in charge of a hospital shall permit a controlled drug to be sold, provided or administered except in accordance with this section.

(2) On receipt of a prescription or a written order signed and dated by a practitioner, the person in charge of a hospital may permit a controlled drug to be administered to a person or an animal under treatment as an in-patient or out-patient of the hospital, or to be sold or provided to the person or to the person in charge of the animal.

(3) Subject to subsection (6), the person in charge of a hospital may permit a controlled drug to be provided, for emergency purposes, to a hospital employee or a practitioner in another hospital on receipt of a written order signed and dated by a pharmacist in the other hospital or a practitioner authorized by the person in charge of the other hospital to sign the order.

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(4) Subject to subjection (6), the person in charge of a hospital may permit a controlled drug to be sold or provided, for emergency purposes, to a pharmacist on receipt of a written order signed and dated by the pharmacist.

(5) The person in charge of a hospital may permit a controlled drug to be provided to a person employed in a research laboratory in that hospital for the purpose of research.

(6) No person in charge of a hospital shall permit a controlled drug to be sold or provided under subsection (3) or (4) unless the signature of the pharmacist in the other hospital or of the practitioner authorized by the person in charge of the other hospital to sign an order is known to the person who sells or provides the controlled drug or has been verified.

4-5-78 **G.05.004.** A person who is in charge of a hospital shall take all steps necessary to protect controlled drugs in the hospital against loss or theft and shall report to the Minister any loss or theft of a controlled drug within ten days of his discovery thereof.

Authority and Penalty

11-3-99 **G.06.001.** (1) Repealed by P.C. 1999-419 of March 11, 1999.

(2) Repealed by P.C. 1999-419 of March 11, 1999.

26-10-04 (3) Despite anything in these Regulations, a person may, for the purpose of identification or analysis of a controlled drug in their possession, provide or deliver the drug to

(a) a practitioner of medicine, or
11-3-99 (b) an agent of a practitioner of medicine, where the agent has been exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to the possession of that controlled drug.

26-10-04 (4) If an agent of a practitioner of medicine receives a controlled drug under subsection (3), they shall immediately provide or deliver it

24-8-72 (a) to the practitioner of whom he is the agent; or
(b) to the Minister or his agent.

26-10-04 (5) A practitioner of medicine who receives a controlled drug under subsection (3) or (4) shall immediately provide or deliver it

11-3-99 (a) for the purpose of identification or analysis thereof, to a person exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to the possession of that controlled drug for that purpose; or
(b) to the Minister or his agent.

11-3-99 **G.06.002.** Every person who is exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to the possession or administration, as the case may be, of a controlled drug shall

13-6-85 (a) keep and retain for a period of two years from the date of the making of the record, a record of
(i) the kind, date and quantity of any controlled drug purchased or received by him;
(ii) the name and address of the person from whom the controlled drug was received; and
(iii) particulars of the use to which the controlled drug was put; and
(b) furnish such information respecting such controlled drugs as the Minister may require, and shall permit access to the records required to be kept by this Part.

Test Kits Containing Controlled Drugs

G.06.002.1 Any person may sell, possess or otherwise deal in a test kit that contains a controlled drug if

(a) a registration number has been issued for the test kit pursuant to section G.06.002.3;
(b) the test kit bears, on its external surface,
26-10-04 (i) the name of the producer, maker or assembler,
(ii) the trade name or trade mark, and
(iii) the registration number issued therefor pursuant to section G.06.002.3;
(c) the test kit is sold, possessed or otherwise dealt in for the purpose of medical, laboratory, industrial, educational or research use; and
(d) the registration number has not been cancelled pursuant to section G.06.002.4.

G.06.002.2 The manufacturer of a test kit that contains a controlled drug may apply for a registration number therefor by submitting to the Director an application containing

(a) particulars of the design and construction of the test kit;
(b) a detailed description of the controlled drug and other substances, if any, contained in the test kit, including the qualitative and quantitative composition of each component;
(c) a statement of the proposed use of the test kit; and
14-7-77 (d) any further information and material that the Minister may require in order to satisfy himself that the test kit is one of which a registration number may be issued.

G.06.002.3 Where, on application under section G.06.002.2, the Minister is satisfied that the test kit to which the application applies will only be used for medical, laboratory, industrial, educational or research use and that it

(a) contains a controlled drug and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion or concentration that the preparation or mixture has no significant drug abuse potential, or
18-12-80 (b) contains such small quantities or concentrations of any controlled drug as to have no significant drug abuse potential,

the Minister may issue a registration number for the test kit, which shall be a number preceded by the letters "TK".

Revoked by P.C. 1980-3469 of December 18, 1980.

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G.06.002.4 The Minister may cancel the registration number for a test kit if the test kit is removed from the market, by the manufacturer or if, in the Minister's opinion,

(a) it is necessary to cancel the registration number in the interest of public health; or
(b) the test kit is used or is likely to be used for any purpose other than medical, laboratory, industrial, educational or research use.

G.06.003. Any person who violates any provision of the **Part** is guilty of an offence and is liable on summary conviction to a fine not exceeding five hundred dollars or to a term of imprisonment not exceeding six months, or to both such fine and imprisonment.

General

14-01-82 **G.07.001.** (1) In this section,

"**member**" means any person who is registered, certified or otherwise licensed by a nursing statutory body for the practice of nursing;

"**nursing statutory body**" means any provincial professional licensing authority that, pursuant to the laws of that province, registers, certifies or otherwise licenses a person for the practice of nursing.

14-5-97 (2) The Minister may provide to a nursing statutory body any information obtained under the *Controlled Drugs and Substances Act*, the *Food and Drugs Act* or these Regulations that involves any member of that body.

14-5-97 **G.07.002.** Where, pursuant to the *Controlled Drugs and Substances Act (Police Enforcement) Regulations*, a member of a police force or a person acting under the direction and control of the member is, in respect of the conduct of the member or person, exempt from the application of subsection 4(2) or section 5, 6 or 7 of the *Controlled Drugs and Substances Act*, the member or person is, in respect of that conduct, exempt from the application of this part.

SCHEDULE

(Sections G.01.001 and G.01.004, subsection G.02.014(3), subparagraph G.02.025(1)(b)(iii), subsections G.02.025(3.2) and (4) and G.03.001(3), paragraph G.03.006(a) section G.03.007 and subsection G.05.001(4))

PART I

1. Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, excluding those substances set out in item 1 of the schedule to Part J but including:
   (1) amphetamine (α–methylbenzeneethanamine)
   (2) methamphetamine (N,α–dimethylbenzeneethanamine)
   (3) Benzphetamine (N–benzyl–N,α–dimethylbenzeneethanamine)
2. Methylphenidate (α–phenyl–2–piperidineacetic acid methyl ester) and any salt thereof
3. Methaqualone (2–methyl–3–(2–methylphenyl)–4(3H)quinazolinone) and any salt thereof
4. Phendimetrazine (d–3,4–dimethyl–2–phenylmorpholine) and any salt thereof
5. Phenmetrazine (3–methyl–2–phenylmorpholine) and any salt thereof

14-5-97 6. Pentobarbital (5–ethyl–5–(1–methylbutyl)barbituric acid)

7. Secobarbital (5–allyl–5–(1–methylbutyl)barbituric acid)

28-10-99 8. 4-hydroxybutanoic acid (GHB) and any salt thereof

9. Aminorex (4,5-dihydro-5-phenyl-2-oxazolamine) and any salt thereof
10. Fenetylline (d,l-3,7-dihydro-1,3-dimethyl-7-(2-[(1-methyl-2-phenethyl)amino]ethyl)-1H-purine-2,6-dione) and any salt thereof
11. Glutethimide (2-ethyl-2-phenylglutarimide)

30-1-03 12. Lefetamine((-)-N,N-dimethyl-α-phenylbenzeneethanamine) and any salt thereof

13. Mecloqualone (2-methyl-3-(2-chlorophenyl)-4(3H)-quinazolinone) and any salt thereof
14. Mesocarb (3-(α-methylphenethyl)-N-(phenylcarbamoyl)sydnone imine) and any salt thereof
15. Pemoline (2-amino-5-phenyl-oxazolin-4-one) and any salt thereof
16. Zipeprol (4-(2-methoxy-2-phenylethyl)-α-(methoxyphenylmethyl)-1-piperazineethanol) and any salt thereof

11-12-03 17. Amineptine (7-[10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid) and any salt thereof

PART II

1. Barbiturates, their salts and derivatives, excluding the substances set out in items 6 and 7 of Part I but including:
   - (1) Allobarbital (5,5-diallylbarbituric acid)
   - (2) Alphenal (5–allyl–5–phenylbarbituric acid)
   - (3) Amobarbital (5–ethyl–5–(3–methylbutyl)barbituric acid)
   - (4) Aprobarbital (5–allyl–5–isopropylbarbituric acid)
   - (5) Barbital (5,5–diethylbarbituric acid)
   - (6) Barbituric Acid (2,4,6(1H,3H,5H)–pyrimidinetrione)
   - (7) Butabarbital (5–sec–butyl–5–ethylbarbituric acid)
   - (8) Butalbital (5–allyl–5–isobutylbarbituric acid)
   - (9) Butallylonal (5–(2–bromoallyl)–5–sec–butylbarbituric acid)
   - (10) Butethal (5–butyl–5–ethylbarbituric acid)
   - (11) Cyclobarbital (5–(1–cyclohexen–1–yl)–5–ethylbarbituric acid)
   - (12) Cyclopal (5–allyl–5–(2–cyclopenten–1–yl)barbituric acid)
   - (13) Heptabarbital (5–(1–cyclohepten–1–yl)–5–ethylbarbituric acid)

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   - (14) Hexethal (5–ethyl–5–hexylbarbituric acid)
   - (15) Hexobarbital (5–(1–cyclohexen–1–yl)–1,5–dimethylbarbituric acid)
   - (16) Mephobarbital (5-ethyl-1-methyl-5-phenylbarbituric acid)
   - (17) Methabarbital (5,5–diethyl–1–methylbarbituric acid)
   - (18) Methylphenobarbital (5–ethyl–1–methyl–5–phenylbarbituric acid)
   - (19) Propallylonal (5–(2–bromoallyl)–5–isopropyl–barbituric acid)
   - (20) Phenobarbital (5–ethyl–5–phenylbarbituric acid)
   - (21) Probarbital (5–ethyl–5–isopropylbarbituric acid)
   - (22) Phenylmethylbarbituric Acid (5–methyl–5–phenylbarbituric acid)
   - (23) Sigmodal(5–(2–bromoallyl)–5–(1–methylbutyl)- barbituric acid)
   - (24) Talbutal (5–allyl–5–sec–butylbarbituric acid)
   - (25) Vinbarbital (5–ethyl–5–(1–methyl–1–butenyl)barbituric acid)
   - (26) Vinylbital (5–(1–methylbutyl)–5–vinylbarbituric acid)

2. Thiobarbiturates, their salts and derivatives, including:
   - (1) Thialbarbital (5–allyl–5–(2–cyclohexen–1–yl)–2–thiobarbituric acid)
   - (2) Thiamylal (5–allyl–5–(1–methylbutyl)–2–thiobarbituric acid)
   - (3) Thiobarbituric Acid (2–thiobarbituric acid)
   - (4) Thiopental(5–ethyl–5–(1–methylbutyl)–2– thiobarbituric acid)

3. Chlorphentermine (1–(p–chlorophenyl)–2–methyl2–aminopropane) and any salt thereof
4. Diethylpropion (2–(diethylamino)propiophenone) and any salt thereof
5. Phentermine (α,α–dimethylbenzeneethanamine) and any salt thereof
6. Butorphanol (1-N-cyclobutylmethyl-3,14-dihydroxy–morphinan) and any salt thereof
7. Nalbuphine (N–cyclobutylmethyl–4,5–epoxy–mor-phinan–3,6,14–triol) and any salt thereof

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8. Pyrovalerone (4'-methyl-2-(1-pyrrolidinyl)valerophenone) and any salt thereof

PART III

1. Anabolic steroids and their derivatives, including:
   - (1) Androisoxazole (17β–hydroxy–17α–methylandrostano[3,2–c]isoxazole)
   - (2) Androstanolone (17β–hydroxy–5α–androstan–3–one)
   - (3) Androstenediol (androst–5–ene–3β,17β–diol)

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   - (4) Bolandiol (estr–4–ene–3β,17β–diol)
   - (5) Bolasterone (17β–hydroxy–7α,17–dimethylandrost–4–en–3–one)
   - (6) Bolazine (17β–hydroxy–2α–methyl–5α–androstan–3–one azine)
   - (7) Boldenone (17β–hydroxyandrosta–1,4–dien–3-one)
   - (8) Bolenol (19–nor–17α–pregn–5–en–17–ol)
   - (9) Calusterone (17β–hydroxy–7β,17–dimethylandrost–4–en–3–one)
   - (10) Clostebol (4–chloro–17β–hydroxyandrost–4–en–3–one)

(11) Drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one)
(12) Enestebol (4, 17β-dihydroxy-17-methylandrosta-1,4-dien-3-one)
(13) Epitiostanol (2α, 3α-epithio-5α-androstan-17β-ol)
(14) Ethylestrenol (19-nor-17α-pregn-4-en-17-ol)
(15) 4-Hydroxy-19-nor testosterone
(16) Fluoxymesterone (9-fluoro-11β,17β-dihydroxy-17-methylandrost-4-en-3-one)
(17) Formebolone (11α,17β-dihydroxy-17-methyl-3-oxoandrosta-1,4-dien-2-carboxaldehyde)
(18) Furazabol (17-methyl-5α-androstano[2,3-c]furazan-17β-ol)
(19) Mebolazine (17β-hydroxy-2α,17-dimethyl-5α-androstan-3-one azine)
(20) Mesabolone (17β-[(1-methoxycyclohexyl)oxy]-5α-androst-1-en-3-one)
(21) Mesterolone (17β-hydroxy-1α-methyl-5α-androstan-3-one)
(22) Metandienone (17β-hydroxy-17-methylandrosta-1,4-dien-3-one)
(23) Metenolone (17β-hydroxy-1-methyl-5α-androst-1-en-3-one)
(24) Methandriol (17α-methylandrost-5-ene-3β,17β-diol)
(25) Methyltestosterone (17β-hydroxy-17-methyl-androst-4-en-3-one)
(26) Metribolone (17β-hydroxy-17-methylestra-4,- 9,11-trien-3-one)
(27) Mibolerone (17β-hydroxy-7α,17-dimethylestr-4-en-3-one)
14-5-97 (28) Nandrolone (17β-hydroxyestr-4-en-3-one)
(29) Norboletone (13-ethyl-17β-hydroxy-18,- 19-dinorpregn-4-en-3-one)
(30) Norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one)
(31) Norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one)
(32) Oxabolone (4,17β-dihydroxyestr-4-en-3-one)
(33) Oxandrolone (17β-hydroxy-17-methyl-2-oxa-5α-androstan-3-one)
(34) Oxymesterone (4,17β-dihydroxy-17-methylandrost-4-en-3-one)
(35) Oxymetholone (17β-hydroxy-2-(hydroxymethylene)-17-methyl-5α-androstan-3-one)
(36) Prasterone (3β-hydroxyandrost-5-en-17-one)
(37) Quinbolone (17β-(1-cyclopenten-1-yloxy)androsta-1,4-dien-3-one)
(38) Stanozolol (17β-hydroxy-17-methyl-5α-androstano[3,2-c]pyrazole)
(39) Stenbolone (17β-hydroxy-2-methyl-5α-androst-1-en-3-one)
(40) Testosterone (17β-hydroxyandrost-4-en-3-one)
(41) Tibolone ((7α,17α)-17-hydroxy-7-methyl-19-norpregn-5(10)en-20-yn-3-one)
(42) Tiomesterone (1α,7α-bis(acetylthio)-17β-hydroxy-17-methylandrost-4-en-3-one)
(43) Trenbolone (17β-hydroxyestra-4,9,11-trien-3-one)

2. Zeranol (3,4,5,6,7,8,9,10,11,12-decahydro-7,14,16-trihydroxy-3-methyl-1H-2-benzoxacyclotetradecin-1-one)

General

J.01.001. In this Part,

26-10-04 "**competent authority**" means a public authority of a foreign country that is authorized under the laws of the country to approve the importation or exportation of restricted drugs into or from the country; (*autorité compétente*)

"**institution**" means any institution engaged in research on drugs and includes a hospital that is licensed by a province, a university, a department or agency of the Government of Canada or of a province or any part thereof;

26-10-04 "**international obligation**" means an obligation in respect of a restricted drug set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres; (*obligation internationale*)

26-10-04 "**licence**" Repealed by P.C. 2004-1238 of October 26, 2004.

"**licensed dealer**" means the holder of a licence issued under section J.01.007.2; (*distributeur autorisé*)

"**permit**" means a permit issued under section J.01.005;

3-11-70 "**practitioner**" means a person who is registered and entitled under the laws of a pr ovince to practise the profession of medicine; and

"**qualified investigator**" means, in respect to a restricted drug, a person who

(i) is employed by or is connected with an institution, or

(ii) is engaged in research in an institution in respect to that drug,

and whose use and possession of that drug is authorized by the Minister pursuant to section J.01.018;

26-10-04 "**qualified person in charge**" means the individual with the qualifications specified in subsection J.01.003.2(2) who is responsible for supervising the activities carried out by a licensed dealer under their licence at the premises specified in the licence: (*personnel qualifiée responsable*)

14-5-97 "**restricted drug**" means a drug set out in the schedule to this Part; (*drogue d'usage restreint*)

"**test kit**" means an apparatus

(i) that contains reagent systems or buffering agents or both,

14-7-77 (ii) that is used in the course of a chemical or analytical procedure for medical, laboratory, industrial, educational or research purposes, and

(iii) the contents of which are not intended for administration to humans.

Possession

14-5-97 **J.01.002.** (1) The following persons may have a restricted drug in their possession;

(a) a licensed dealer;

(b) a qualified investigator if he has possession for the purpose of and in connection with research in an institution;

(c) an analyst, inspector, member of the Royal Canadian Mounted Police, constable, peace officer, member of the staff of the Department of National Health and Welfare or officer of a court, if such person has possession for the purpose and in connection with his employment; and

11-3-99 (d) a person exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to that restricted drug.

(2) A person is authorized to have a restricted drug in his possession if the person is acting as the agent for a person referred to in paragraph (1)(a),(b) or (d).

14-5-97 (2.1) A person is authorized to have a restricted drug in his possession where

(a) the person is acting as the agent for a person he has reasonable grounds to believe is a person referred to in paragraph (1)(c); and

(b) the possession of the restricted drug is for the purpose of assisting that person in the enforcement or administration of an Act or regulation.

J.01.003. Subject to this Part, no person except a licensed dealer shall produce, make, assemble, import, export, sell, provide, transport, send or deliver a restricted drug.

J.01.003.1. To be eligible for a dealer's licence, a person must be

(a) an individual who ordinarily resides in Canada;
(b) a corporation that has its head office in Canada or operates a branch office in Canada; or
(c) the holder of a position that includes responsibility for restricted drugs on behalf of a department of the Government of Canada or of a government of a province, a police force, a hospital or a university in Canada.

J.01.003.2. (1) A licensed dealer

(a) shall designate no more than one qualified person in charge, who may be the licensed dealer if the licensed dealer is an individual, who must work at the premises specified in the licence, have responsibility for supervising activities with respect to restricted drugs specified in the licence and for ensuring, on behalf of the licensed dealer, that those activities comply with these Regulations; and
26-10-04 (b) may designate an alternate qualified person in charge who must work at the premises set out in the licence and have authority to replace the qualified person in charge when that person is absent.

(2) The qualified person in charge and, if applicable, the alternate qualified person in charge

(a) shall be familiar with the provisions of the Act and the regulations under it that apply to the licence of the licensed dealer who designated them and have knowledge of chemistry and pharmacology and experience in those fields to properly carry out their duties;
(b) shall be a pharmacist or a practitioner registered with a licensing body of a province or possess a degree in an applicable science — such as pharmacy, medicine, dentistry, veterinary medicine, pharmacology, organic chemistry or chemical engineering — that is awarded by a Canadian university or, if awarded by a foreign university, that is recognized by a Canadian university or a Canadian professional association; and
(c) shall not have been convicted, as an adult, within the previous 10 years, of
  (i) a designated drug offence,
  (ii) a designated criminal offence, or
  (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii).

J.01.004. No licensed dealer shall import or export a restricted drug without a permit.

17-12-97 **J.01.004.1** A licensed dealer is authorized to have a restricted drug in his possession for the purpose of exporting the restricted drug from Canada if he has obtained the restricted drug pursuant to these Regulations.

J.01.005. The Minister may, upon application therefor, after such investigation as he deems proper and subject to such terms and conditions as he deems proper, issue to any licensed dealer a permit for the importation or exportation of a restricted drug.

J.01.006. An application for a permit shall be in a form approved by the Minister.

J.01.007. (1) To apply for a dealer's licence, a person shall submit an application to the Minister containing

(a) if the licence is sought for
  (i) an individual, the individual's name,
  (ii) a corporation, the corporation's name and any other name registered with a province, under which it intends to carry out the activities specified in its dealer's licence or intends to identify itself; and
  (iii) the holder of a position mentioned in paragraph J.01.003.1(c), the applicant's name and the title of the position;
(b) the address, telephone number and, if applicable, the facsimile transmission number and e-mail address for the premises to which the dealer's licence would apply and, if different, the mailing address for the premises;
(c) the name, date of birth and gender of the individual in charge of the premises;
(d) with respect to the qualified person in charge and, if applicable, the alternate qualified person in charge at the premises,
  (i) their name, date of birth and gender,
  (ii) their academic qualifications, training and work experience relevant to their duties,
  (iii) their hours of work, at the premises,
  (iv) their title at the premises,
  (v) the name and title of their immediate supervisor at the premises, and
  (vi) in the case of a pharmacist or a practitioner, the name of the pr ovince in which the person's current professional licence, certification or authorization was issued and the professional licence, certification or authorization number;
(e) the name and gender of the individuals authorized to place an order for a restricted drug on behalf of the applicant;
(f) the activities referred to in section J.01.003 for which the licence is sought that would be carried out at the premises to which the dealer's licence would apply;
(g) in the case of a product or compound that contains a restricted drug but is not a test kit and that would be made or assembled for or by the applicant, a list that sets out
  (i) the name, number or identifying mark, if any, of each product or compound,
  (ii) the restricted drug in each product or compound,
  (iii) the strength per unit of the restricted drug in each product or compound,
  (iv) the quantity or package sizes of each product or compound, and
  (v) if the product or compound would be made or assembled by or for another licensed dealer under a custom order, the name, address and the dealer's licence number of the other dealer;

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(h) if the licence is sought to pr oduce a restricted drug other than a product or compound that contains a restricted drug
  (i) the restricted drug to be produced,
  (ii) the quantity that the applicant expects to produce under the dealer's licence and the period during which that quantity would be produced, and
  (iii) if the restricted drug would be produced for another licensed dealer under a custom order, the name, address and licence number of the other dealer;
(i) a detailed description of the security measures at the premises, determined in accordance with the Security Directive;
(j) a detailed description of the method that the applicant pr oposes to use for recording their restricted drug transactions; and
(k) for any activity referred to in section J.01.003, other than the activities described in paragraphs (g) and (h), the restricted drug and the purpose for carrying out the activity.

(2) An application for a dealer's licence must

(a) be signed by the individual in charge of the premises to which the licence would apply; and
(b) be accompanied by a statement signed by the individual in charge indicating that
  (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
  (ii) the individual in charge has the authority to bind the applicant.

(3) An application for a dealer's licence must be accompanied by

(a) declarations signed by the individual in charge of the premises, the qualified person in charge and, if applicable, the alternate qualified person in charge, stating that they have not been convicted, as an adult, during the previous 10 years of
  (i) a designated drug offence,
  (ii) a designated criminal offence, or
  (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(b) a document issued by a Canadian police force with respect to each of the persons referred to in paragraph (a), stating whether the person has or has not been convicted, as an adult, during the preceding 10 years of a designated drug offence or a designated criminal offence;
(c) if any of the persons referred to in paragraph (a) has ordinarily resided in a country other than Canada during the preceding 10 years, a document issued by a police force of that country stating whether the person has or has not been convicted in that country, as an adult, during the preceding 10 years, of an offence that would have constituted a designated drug offence or a designated criminal offence if committed in Canada;
(d) a statement, signed and dated by the individual in charge of the premises, stating that the qualified person in charge and, if applicable, the alternate qualified person in charge have the knowledge and experience required under paragraph J.01.003.2(2)(a);
(e) if the qualified person in charge or, if applicable, the alternate qualified person in charge is not a pharmacist or a practitioner registered with a licensing body of a province, a copy of the person's degree required under paragraph J.01.003.2(2)(b) and a copy of the course transcript for that degree;
(f) if the applicant's name appears on the label of a product or compound that contains a restricted drug, a copy of the inner label, as defined in section A.01.010, for each product or compound to which the licence would apply; and
(g) if the applicant is a corporation, a copy of
    (i) the certificate of incorporation or other constituting instrument, and
    (ii) any document filed with the province in which the premises to which the licence would apply are located that states its corporate name or any other name registered with the province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself.

(4) The method proposed by the applicant under paragraph (1)(j) must

(a) allow for the recording of restricted drug transactions in accordance with section J.01.021; and
(b) permit the Minister to audit the activities of the licensed dealer with respect to restricted drugs.

(5) The documents referred to in paragraphs (3)(b) and (c) are not required if the persons referred to in those paragraphs consent in writing

(a) to having a criminal record check carried out for them, as an adult, in respect of the offences referred to in those paragraphs during the preceding 10 years;
(b) to provide all information and to submit to any means of identification required to obtain criminal record check; and
(c) to pay the fee established by the *Royal Canadian Mounted Police, Criminal Record Verification for Civil Purposes Fee Regulations*.

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J.01.007.1. The Minister may, on receiving an application made under this Part, require the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to process the application.

J.01.007.2. Subject to section J.01.007.3, the Minister shall, after examining the infor mation and documents required under sections J.01.007 and J.01.007.1, issue a dealer's licence that contains

(a) the licence number;
(b) the name of the applicant or the title of the position they hold, as the case may be, or, if the applicant is a corporation, its corporate name;
(c) a list of the activities that are permitted;
(d) the address of the premises at which the licensed dealer may carry on the permitted activities;
(e) the name of the restricted drug for which the activities are permitted;
(f) the security level at the premises;
(g) the effective date of the licence;
(h) the expiry date of the licence, which may not be later than three years after its effective date;
(i) any conditions to be met by the holder of the licence to
    (i) ensure that an international obligation is respected,
    (ii) provide the security level referred to in paragraph (f), or
    (iii) reduce the potential security, public health or safety hazard, including the risk of the restricted drug being diverted to an illicit market or use;
(j) in the case of a producer of a restricted drug, the quantity of the restricted drug that may be produced under the licence and the period during which that quantity may be produced; and

(k) in the case of the maker or assembler of a product or compound that contains a restricted drug but is not a test kit, an annexed list that sets out the following information for each type of product or compound that may be made or assembled under the licence:
(i) the licence number,
(ii) the name, number or identifying mark, if any, of each product or compound,
(iii) the restricted drug in each product or compound,
(iv) the strength per unit of the restricted drug in each product or compound, and
(v) the quantity or package sizes of each product or compound.

J.01.007.3. (1) The Minister shall refuse to issue, renew or amend a dealer's licence if

(a) the applicant is not eligible under section J.01.003.1;
(b) an inspector who has requested an inspection has not been given the opportunity by the applicant to conduct an inspection under section J.01.025;
(c) false or misleading information or false or falsified documents were submitted in or with the application;
(d) an activity for which the licence is requested would not be in compliance with an international obligation;
(e) information received from a competent authority or the United Nations raises a reasonable belief that the applicant has been involved in the diversion of a restricted drug to an illicit market or use or has been involved in an activity that was not in compliance with an international obligation;
(f) the applicant does not have in place the security measures set out in the Security Directive in respect of an activity for which the licence is requested;
(g) the applicant is in contravention of or has contravened during the preceding 10 years
(i) a provision of the Act or any regulations made or continued under the Act, or
(ii) a term or condition of another dealer's licence or of an import or export permit issued to the applicant under any regulations made or continued under the Act;
(h) the issuance, amendment or renewal of the licence would likely create a risk to public health, safety or security, including the risk of a restricted drug being diverted to an illicit market or use;
(i) the individual in charge of the premises, the qualified person in charge or , if applicable, the alternate qualified person in charge has been convicted, as an adult, within the previous 10 years, of
(i) a designated drug offence,
(ii) a designated criminal offence, or
(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);
26-10-04 (j) the proposed method referred to in paragraph J.01.007(1)(j) is not capable of recording the applicant's restricted drug transactions as required under section J.01.023 or permitting the Minister to audit the applicant's activities with respect to restricted drugs in a timely manner; or
(k) the additional information required under section J.01.007.1 has not been provided or is insufficient to process the application.

(2) The Minister is not required to refuse to issue, renew or amend a licence under paragraph (1)(c) or (g) if the applicant

(a) does not have a history of non-compliance with the Act or any regulation made or continued under it; and
(b) has carried out, or signed an undertaking to carry out, specified corrective measures to ensure compliance with the Act and these Regulations.

J.01.007.4. (1) To apply to renew a dealer's licence, a licensed dealer must submit to the Minister

(a) the information required under paragraphs J.01.007(1)(a) to (k); and
(b) the following documents, namely,
(i) the documents referred to in paragraphs J.01.007(3)(a) and (d) and, subject to subsection J.01.007(5), the document specified in paragraph J.01.007(3)(b),
(ii) if applicable and if not previously submitted in respect of the dealer's licence that is being renewed, the document referred to in paragraph J.01.007(3)(e), and
(iii) the original dealer's licence that is to be renewed.

(2) An application for renewal must

(a) be signed by the individual in charge of the premises to which the renewed dealer's licence would apply; and
(b) be accompanied by a statement signed by the individual in charge indicating that
(i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
(ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section J.01.007.3, the Minister shall, after examining the information and documents required under subsections (1) and (2) and section J.01.007.1, issue a renewed dealer's licence that contains the information specified in paragraphs J.01.007.2(a) to (k).

J.01.007.5. (1) To have its dealer's licence amended, a licensed dealer shall submit to the Minister

(a) an application in writing describing the proposed amendment, accompanied by the supporting documents referred to in section J.01.007 that are relevant to the proposed amendment; and
(b) the original dealer's licence.

(2) An application for amendment must

(a) be signed by the individual in charge of the premises to which the amended dealer's licence would apply; and
(b) be accompanied by a statement signed by the individual in charge indicating that
  (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
  (ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section J.01.007.3, the Minister shall, after examining the request for amendment and the supporting documentation, amend the dealer's licence in accordance with the request and may add any conditions to be met by the holder of the licence to

(a) ensure that an international obligation is respected;
(b) provide for the security level referred to in paragraph J.01.007.2(f) or the new level required as a result of the amendment being implemented; or
(c) reduce the potential security, public health or safety hazard, including the risk of the restricted drug being diverted to an illicit market or use.

J.01.007.6. (1) A licensed dealer shall

(a) obtain the Minister's approval before making any of the following changes, namely,
  (i) a change relating to the security at the premises referred to in the dealer's licence, or
  (ii) the replacement of the addition of
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    (A) an individual in charge of the premises to which the dealer's licence applies,
    (B) a qualified person in charge and, if applicable, an alter nate qualified person in charge at the premises to which the dealer's licence applies, and
    (C) an individual authorized to place an order for a restricted drug on behalf of the licensed dealer;
(b) notify the Minister, not later than 10 days after the change, when a person referred to in clause (a)(ii)(A) or (C) ceases to carry out their duties as specified in
  (i) the application for a dealer's licence under section J.01.007,
  (ii) the application to renew a dealer's licence under section J.01.007.4, or
  (iii) the request for approval under paragraph (a); and
(c) notify the Minister, not later than the next business day after the change, when a person referred to in clause (a)(ii)(B) ceases to carry out their duties as specified in
  (i) the application for a dealer's licence under section J.01.007,
  (ii) the application to renew a dealer's licence under section J.01.007.4, or
  (iii) the request for approval under paragraph (a).

(2) The licensed dealer shall, with the request for appr oval referred to in subparagraph (1)(a)(ii), provide the Minister with the following information and documents with respect to the new person:

(a) in the case of the replacement of the individual in charge of the premises to which the dealer's licence applies,
  (i) the information specified in paragraph J.01.007(1)(c), and
  (ii) the declarations specified in paragraph J.01.007(3)(a) and, subject to subsection J.01.007(5), the documents specified in paragraphs J.01.007(3)(b) and (c);
(b) in the case of the replacement of the qualified person in charge or the replacement or addition of the alternate qualified person in charge at the premises to which the dealer's licence applies,
  (i) the information specified in paragraph J.01.007(1)(d), and
  (ii) the documents specified in paragraphs J.01.007(3)(a), (d) and (e) and, subject to subsection J.01.007(5), the documents specified in paragraphs J.01.007(3)(b) and (c); and
(c) in the case of the replacement or addition of an individual who is authorized to place an order for a restricted drug on behalf of the licensed dealer, the individual's name and gender.

J.01.007.7. The Minister shall revoke a dealer's licence at the request of the licensed dealer or on being notified by the licensed dealer that the licence has been lost or stolen.

J.01.007.8. (1) Subject to subsection (2), the Minister shall revoke a dealer's licence in accordance with section J.01.007.91 if

(a) the licence was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application;
(b) the licensed dealer has failed to comply with a provision of the Act, a regulation under it or a ter m or condition of the licence or of an import or export permit issued under this Part;
(c) the licensed dealer is no longer an eligible person under section J.01.003.1;
(d) it is discovered that the individual in charge of the premises to which the licence applies, the qualified person in charge or, if applicable, the alter nate qualified person in charge at those premises, has been convicted, as an adult, within the previous 10 years, of
  (i) a designated drug offence,
  (ii) a designated criminal offence, or
  (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii); or
(e) information received from a competent authority or the United Nations raises a reasonable belief that the licensed dealer has been involved in the diversion of a restricted drug to an illicit market or use.

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(2) The Minister is not required to revoke a dealer's licence under paragraph (1)(a) or (b) if the licensed dealer

(a) has no history of non-compliance with the Act and the regulations made or continued under it; and
(b) has carried out, or signed an undertaking to carry out, corrective measures to ensure compliance with the Act and these Regulations.

J.01.007.9. The Minister shall suspend a dealer's licence without prior notice if it is necessary to do so to protect security, public health or safety, including preventing a restricted drug from being diverted to an illicit market or use.

J.01.007.91. (1) If the Minister proposes to refuse to issue, amend or renew, or proposes to revoke, a licence under this Part, the Minister shall

(a) send a notice to the applicant or to the holder of the licence, together with a written report that sets out the reasons for the proposed refusal or revocation; and
(b) give the applicant or holder an opportunity to be heard in respect of the proposed refusal or revocation.

(2) The suspension of a licence under this Part takes effect as soon as the Minister informs the holder of the licence of the decision to suspend and provides a written report that sets out the reasons for the suspension.

(3) A person who receives a notice of suspension referred to in subsection (2) may, in the 10 days following the receipt of the notice, provide the Minister with reasons why the suspension of the licence is unfounded.

J.01.009. The Minister may impose such restrictions and conditions on a licensed dealer as he deems necessary for the control of a restricted drug.

J.01.010. A licensed dealer may at any time make an application to the Minister to amend his licence in order to become a licensed dealer in respect of a restricted drug other than a restricted drug specified in his licence or to change the terms or conditions of his licence.

J.01.011. A licensed dealer may, subject to the terms and conditions of their licence, produce, make, assemble, sell, provide, transport, send or deliver only the restricted drugs specified in their dealer's licence.

26-10-04 **J.01.012.** The Minister shall revoke or suspend a permit issued under this Part if the Minister determines that the person to whom it was issued has failed to comply with any term or condition of the permit or any provision of this Part.

J.01.013. A dealer's licence is valid until the earlier of

(a) the expiry date set out in the licence, and
(b) the revocation or suspension of the licence under section J.01.007.7, J.01.007.8 or J.01.007.9.

J.01.014. A permit is valid only for the particular importation or exportation in respect of which it was issued.

Sale of a Restricted Drug

J.01.015. An institution may, in a form approved by the Minister make an application to a licensed dealer or to the Minister with respect to the purchase of a restricted drug

(a) for clinical use in the institution by qualified investigators for the purpose of determining the hazards and efficacy of the drug; or
(b) for laboratory research in the institution by qualified investigators.

J.01.016. Where a licensed dealer receives an application made pursuant to section J.01.015, he shall, before selling a restricted drug to the institution that made the application

(a) supply the Minister with a copy of the application; and
(b) obtain the written authority of the Minister to make the proposed sale of the restricted drug.

J.01.017. An application made pursuant to section J.01.015 shall contain

(a) the name and the address of the institution seeking to purchase the drug;
(b) the names and qualifications of the qualified investigators who will use and be in possession of the drug;
(c) the details of the proposed use of the drug;
(d) the quantity of the drug required;
(e) the dosage form of the drug required by the institution; and
(f) the name of the licensed dealer from whom the purchase of the drug will be made.

J.01.018. Where the Minister receives from an institution an application or a copy of an application made pursuant to section J.01.015, he may, subject to such qualifications and limitations as he deems proper, authorize

3-11-70 (a) the sale to the institution by a licensed dealer of the restricted drug applied for in such quantity and such dosage form as he deems proper; and
(b) qualified investigators to make clinical use of the restricted drug in the institution or to carry out laboratory research with the restricted drug in the institution and to possess the restricted drug for the purposes of such use or research.

J.01.019. An institution shall use a restricted drug only for the purpose and in accordance with the pr otocol therefor set out in the application respecting that restricted drug made pursuant to section J.01.015.

J.01.020. Where a licensed dealer is authorized under section J.01.018, to sell a restricted drug, he may, notwithstanding section C.08.002, sell that drug subject to any qualifications or limitations imposed by the Minister.

Records and Inspection

13-6-85 **J.01.021.** Every institution shall keep and retain for a period of two years from the date of the making of the record, a record of

(a) the amount of every restricted drug received by the institution;
(b) details of the use of restricted drugs in the institution;
(c) the names and qualifications of every person who makes use of a restricted drug in the institution; and
(d) full clinical data with respect to the use of every restricted drug received by the institution.

J.01.022. Every institution shall make its records referred to in section J.01.021 available to the Minister upon his request and shall permit such inspection of the institution, respecting its use of restricted drugs, as the Minister may require.

J.01.023. Every licensed dealer shall maintain a record of

(a) the name, quantity and form of any restricted drug received by them, the name and address of the person who sold or provided it and the date it was received;
26-10-04 (b) the name, quantity and form of any restricted drug sold or provided by them, the name and address of the person to whom it was sold or provided and the date it was sold or provided;
(c) the name, quantity and form of any restricted drug they have used in making or assembling a pr oduct or compound containing that restricted drug, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;
(d) the name and quantity of any restricted drug produced and the date on which it was placed in stock; and
(e) the name, quantity and form of any restricted drug he has in stock.

J.01.024. Every licensed dealer and every person who has been a licensed dealer shall keep the record referred to in section J.01.023 on the premises described in the licence that was issued to him or in such other place as may be approved by the Minister, for a period of at least two years and shall keep such record in a form that will facilitate an audit thereof being made at any time.

J.01.025. (1) The Minister may, in respect of an applicant for a dealer's licence or a licensed dealer, require an inspection, at any reasonable time, of

26-10-04 (a) the premises used or intended to be used in producing, making, assembling or storing a restricted drug; and
(b) the process and conditions of the producing, making, assembling or storing.

(2) The Minister may, in respect of a licensed dealer, require a verification to be made, at any reasonable time, of the qualifications of its technical staff concerned with producing, making, assembling or storing a restricted drug.

26-10-04 **J.01.026.** Every person who sells or provides a restricted drug shall

(a) supply such information in such form as the Minister may require respecting the dealings of any person in the restricted drug;
(b) produce to an inspector any books, records or documents required to be kept under this Part;
(c) permit an inspector to make copies of or to take extracts from any books, records and documents; and
(d) permit an inspector to check all stocks of restricted drugs located on the premises described in his licence.

J.01.027. Every licensed dealer shall notify the Minister forthwith of any change

(a) in his technical staff concerned with a restricted drug;
26-10-04 (b) in the premises in which a restricted drug is produced, made, assembled or stored; and
(c) in the process and conditions of producing, making, assembly or storage of a restricted drug.

J.01.028. Every person who is in possession of a restricted drug and every institution to which the sale of a restricted drug has been authorized by the Minister shall

(a) provide such protection against loss or theft of the restricted drug as may be required by the Minister; and
(b) report forthwith to the Minister and to local law enforcement authorities any loss or theft of a restricted drug.

J.01.029. Where a licensed dealer delivers a restricted drug, he shall

(a) take such steps as are necessary to insure the safekeeping of the drug during transit; and
(b) use such methods of transportation as will insure that an accurate record is kept of the drug while in transit and of the signature of any persons having charge of the drug until it is delivered to the consignee.

Packaging and Labelling

J.01.030. Every restricted drug that is sold to an institution shall be securely packed by the licensed dealer who sells the drug in such a manner that the package cannot be opened without breaking the seal.

J.01.031. The provisions of section C.01.004 do not apply to a restricted drug.

J.01.032. Every package that contains a restricted drug shall be labelled so that the inner and outer labels thereon show

(a) the proper name or, if there is no proper name, the common name of the drug;
(b) the net contents of the package;
(c) the unit strength of the drug where it is in unit form;
(d) the lot number of the drug;
(e) the words "Restricted Drug"; and
26-10-04 (f) the name and address of the producer, maker or assembler of the drug.

14-7-77 **J.01.032.1** Section J.01.032 does not apply to a test kit that contains a restricted drug where a registration number has been issued for the test kit pursuant to section J.01.033.3 and has not been cancelled pursuant to section J.01.033.4.

J.01.033. (1) Repealed by P.C. 1999-419 of March 11, 1999.
11-3-99

(2) Repealed by P.C. 1999-419 of March 11, 1999.

26-10-04 (3) Despite anything in these Regulations, a person may, for the purpose of identification or analysis of a restricted drug, provide or deliver the restricted drug that they have in their possession to

(a) a practitioner; or
11-3-99 (b) an agent of a practitioner, where the agent has been exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to the possession of that restricted drug for that purpose.

26-10-04 (4) If an agent of a practitioner has received a restricted drug under subsection (3), the agent shall immediately provide or deliver it

(a) to the practitioner of whom he is the agent; or
24-8-72 (b) to the Minister or his agent.

26-10-04 (5) A practitioner who has received a restricted drug under subsection (3) or (4) shall immediately provide or deliver it

11-3-99 (a) for the purpose of identification or analysis thereof, to a person exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to the possession of that restricted drug for that purpose; or

(b) to the Minister.

11-3-99 (6) Sections J.01.021 and J.01.022 apply with such modifications as the circumstances may require to every person who has received a restricted drug pursuant to this section other than a person to whom a restricted drug has been administered pursuant to an exemption granted under section 56 of the *Controlled Drugs and Substances Act* with respect to the administration of that drug.

Test Kits Containing Restricted Drugs

J.01.033.1 Any person may sell, possess or otherwise deal in a test kit that contains a restricted drug if

(a) a registration number has been issued for the test kit pursuant to section J.01.033.3;

(b) the test kit bears, on its external surface,

26-10-04 (i) the name of the producer, maker or assembler,

(ii) the trade name or trade mark, and

(iii) the registration number issued therefor pursuant to section J.01.033.3;

(c) the test kit is sold, possessed or otherwise dealt in for the purpose of medical, laboratory, industrial, educational or research use; and

(d) the registration number has not been cancelled pursuant to section J.01.033.4.

J.01.033.2 The manufacturer of a test kit that contains a restricted drug may apply for a registration number therefor by submitting to the Director an application containing

(a) particulars of the design and construction of the test kit;

(b) a detailed description of the restricted drug and other substances, if any, contained in the test kit, including the qualitative and quantitative composition of each component;

14-7-77 (c) a statement of the proposed use of the test kit; and

(d) any further information and material that the Minister may require in order to satisfy himself that the test kit is one for which a registration number may be issued.

J.01.033.3 Where, on application under section J.01.033.2, the Minister is satisfied that the test kit to which the application applies will only be used for medical, laboratory, industrial, educational or research use and that it

(a) contains a restricted drug and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion or concentration that the preparation or mixture has no significant drug abuse potential, or

18-12-80 (b) contains such small quantities or concentrations of any restricted drug as to have no significant drug abuse potential,

the Minister may issue a registration number for the test kit, which shall be a number preceded by the letters "TK".

Revoked by P.C. 1980-3469 of December 18, 1980.

J.01.033.4 The Minister may cancel the registration number for a test kit if the test kit is removed from the market by the manufacturer or if, in the Minister's opinion,

(a) it is necessary to cancel the registration number in the interest of public health; or *p2(b) */the test kit is used or is likely to be used for any purpose other than medical, laboratory, industrial, educational or research use.

14-7-77 **Prescribed Manner of Notice of Application for an Order of Restoration**

14-5-97 **J.01.035.** (1) For the purpose of subsection 24(1) of the *Controlled Drugs and Substances Act*, notice of application for an order of restoration shall be given in writing to the Attorney General by registered mail.

(2) The notice referred to in subsection (1) shall be mailed not less than fifteen clear days prior to the date the application is to be made to the magistrate and shall specify

14-7-77

(a) the magistrate to whom the application is to be made;
(b) the time and place where the application is to be heard;
(c) the restricted drug or other thing in respect of which the application is to be made; and
(d) the evidence upon which the applicant intends to rely to establish that he is entitled to possession of the restricted drug or other thing referred to in paragraph (c).

14-5-97 **J.01.036.** Where, pursuant to the *Controlled Drugs and Substances Act (Police Enforcement) Regulations*, a member of a police force or a person acting under the direction and control of the member is, in respect of the conduct of the member or person, exempt from the application of subsection 4(2) or section 5, 6 or 7 of the *Controlled Drugs and Substances Act*, the member or person is, in respect of that conduct, exempt from the application of this Part.

SCHEDULE
(Section J.01.001)

14-5-97 1. The following amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues:

(1) N-ethylamphetamine (N-ethyl-α-methylbenzeneethanamine)
(2) 4-methyl-2,5-dimethoxyamphetamine (STP) (2,5-dimethoxy-4,α-dimethylbenzeneethanamine)
(3) 3,4-methylenedioxyamphetamine (MDA)(α-methyl-1,3-benzodioxole-5-ethanamine)
(4) 2,5-dimethoxyamphetamine(2,5-dimethoxy-α-methylbenzeneethanamine)
(5) 4-methoxyamphetamine (4-methoxy-α-methylbenzeneethanamine)
(6) 2,4,5-trimethoxyamphetamine (2,4,5-trimethoxy-α-methylbenzeneethanamine)
(7) N-methyl-3,4-methylenedioxyamphetamine (N,α-dimethyl-1,3-benzodioxole-5-ethanamine)
(8) 4-ethoxy-2,5-dimethoxyamphetamine (4-ethoxy-2,5-dimethoxy-α-methylbenzeneethanamine)
(9) 5-methoxy-3,4-methylenedioxyamphetamine (7-methoxy-α-methyl-1,3-benzodioxole-5-ethanamine)
(10) N,N-dimethyl-3,4-methylenedioxyamphetamine (N,N, α-trimethyl-1,3-benzodioxole-5-ethanamine)
(11) N-ethyl-3,4-methylenedioxyamphetamine (N-ethyl-α-methyl-1,3-benzodioxole-5-ethanamine)
(12) 4-ethyl-2,5-dimethoxyamphetamine (DOET) (4-ethyl-2,5-dimethoxy-α-methylbenzeneethanamine)
(13) 4-bromo-2,5-dimethoxyamphetamine (4-bromo-2,5-dimethoxy-α-methylbenzeneethanamine)
(14) 4-chloro-2,5-dimethoxyamphetamine (4-chloro-2,5-dimethoxy-α-methylbenzeneethanamine)
(15) 4-ethoxyamphetamine (4-ethoxy-α-methyl-benzeneethanamine)
(16) N-Propyl-3,4-methylenedioxyamphetamine (α-methyl-N-propyl-1,3-benzodioxole-5-ethanamine)
30-1-03 (17) N-hydroxy-3,4-methylenedioxyamphetamine (N-[α-methyl-3,4-(methylenedioxy)phenethyl] hydroxylamine)
(18) 3,4,5-trimethoxyamphetamine (3,4,5-trimethoxy-α-methylbenzeneethanamine)

	2. Lysergic acid diethylamide (LSD) (N,N–diethyllysergamide) and any salt thereof
	3. N,N–Diethyltryptamine (DET) (3–[(2–diethylamino)ethyl]indole) and any salt thereof
	4. N,N–Dimethyltryptamine (DMT) (3–[(2–dimethylamino)ethyl]indole) and any salt thereof
	5. N–Methyl–3–piperidyl benzilate (LBJ) (3–[(hydroxydiphenylacetyl)oxy]–1–methylpiperidine) and any salt thereof
	6. Harmaline (4,9–dihydro–7–methoxy–1–methyl–3H-pyrido(3,4–b)indole) and any salt thereof
	7. Harmalol (4,9–dihydro–1–methyl–3H–pyrido(3,4–b)indol–7–ol) and any salt thereof
	8. Psilocin (3–[2–(dimethylamino)ethyl]–4–hydroxyindole) and any salt thereof
14-5-97	9. Psilocybin (3–[2–(dimethylamino)ethyl]–4–phosphoryloxyindole) and any salt thereof
	10. N–(1–phenylcyclohexyl)ethylamine (PCE) and any salt thereof
	11. 1–[1–(2–Thienyl)cyclohexyl]piperidine (TCP) and any salt thereof
	12. 1–Phenyl–N–propylcyclohexanamine and any salt thereof
	13. Mescaline (3,4,5–trimethoxybenzeneethanamine) and any salt thereof, but not peyote (lophophora)
	14. 4–Methylaminorex (4,5–dihydro–4–methyl–5–phenyl–2–oxazolamine) and any salt thereof
	15. 2–Methylamino–1–phenyl–1–propanone and any salt thereof
	16. 1–[1–(Phenylmethyl)cyclohexyl]piperidine and any salt thereof
	17. 1–[1–(4–Methylphenyl)cyclohexyl]piperidine and any salt thereof
30-1-03	18. Etryptamine (3-(2-aminobutyl)indole) and any salt thereof
	19. Rolicyclidine (1-(1-phenylcyclohexyl) pyrrolidine) and any salt thereof

PART K

Revoked by P.C. 1975-2101 on September 11, 1975.

*(R) Minor correction

14-11-00	Abacavir and its salts *Abacavir et ses sels*
14-5-98	Abciximab *Abciximab*
9-12-97	Acarbose and its derivatives *Acarbose et ses dérivés*
	Acebutolol and its salts *Acébutolol et ses sels*
	Acetazolamide *Acétazolamide*
	Acetohexamide *Acétohexamide*
	Acetylcarbromal *Acétylcarbromal*
	Acetylcholine Chloride *Acétylcholine (chlorure d')*
7-5-96	Acitretin and its salts and derivatives *Acitrétine, ses sels et dérivés*
	Aconiazide and its salts *Aconiazide et ses sels*
	Acyclovir and its salts *Acyclovir et ses sels*
7-5-96	Adapalene and its salts and derivatives *Adapalène, ses sels et dérivés*
31-5-05	Adefovir and its salts and derivatives *Adéfovir, ses sels et dérivés*
	Adenosine and its salts, when sold or recommended for administration by intravenous injection *Adénosine et ses sels, s'il est vendu ou recommandé pour administration par injection intraveineuse*
18-5-00	Alatrofloxacin and its salts and derivatives *Alatrofloxacine et ses sels et dérivés*
7-5-96	Aldesleukin *Aldésleukine*
9-12-97	Alendronic acid and its salts *Alendronique (acide) et ses sels*
	Alfacalcidol *Alfacalcidol*
2-10-03	Alfuzosin and its salts *Alfuzosine et ses sels*
	Alkyl nitrites *Alkyle (nitrites d')*
	Allopurinol *Allopurinol*
	Allylisopropylacetylurea *Allylisopropylacétylurée*
31-5-05	Almotriptan and its salts *Almotriptan et ses sels*
	Alpha-chloralose *Alpha-chloralose*
	Alphadolone and its salts *Alphadolone et ses sels*
	Alphaxalone
13-12-95	*Alfaxalone*
4-5-04	Alteplase and its salts and derivatives *Altéplase, ses sels et dérivés*
	Altrenogest *Altrénogest*
	Altretamine *Altrétamine*
	Amantadine and its salts *Amantadine et ses sels*

	Ambenonium Chloride *Ambénonium (chlorure d')*
4-5-04	Repealed by P.C. 2004-538 of May 4, 2004
14-5-98	Amifostine and its salts *Amifostine et ses sels*
	Amikacin and its salts and derivatives *Amikacine, ses sels et dérivés*
	Amiloride and its salts *Amiloride et ses sels*
	Aminocaproic acid *Aminocaproïque (acide)*
	Aminoglutethimide *Aminoglutéthimide*
18-6-03	Aminolevulinic acid and its salts and derivatives *Aminolévulinique (acide), ses sels et dérivés*
	Aminophylline *Aminophylline*
	Aminopterin and its salts *Aminoptérine et ses sels*
	4-Amino-pteroyl asPARTic acid and its salts *Amino-4-ptéroyl asPARTique (acide) et ses sels*
	5-Aminosalicylic acid *Amino-5-salicylique (acide)*
	4-Aminosalicylic Acid and its salts *Amino-4 salicylique (acide) et ses sels*
	Amiodarone and its salts *Amiodarone et ses sels*
	Amitraz *Amitraz*
	Amitriptyline and its salts *Amitriptyline et ses sels*
18-6-03	Amlexanox and its salts and derivatives *Amlexanox, ses sels et dérivés*
	Amlodipine and its salts *Amlodipine et ses sels*
	Ammonium bromide *Bromure d'ammonium*
	Amoxapine *Amoxapine*
	Amoxicillin and its salts and derivatives *Amoxicilline, ses sels et dérivés*
	Amphotericin B and its salts and derivatives *Amphotéricine B, ses sels et dérivés*
	Ampicillin and its salts and derivatives *Ampicilline, ses sels et dérivés*
2-10-03	Amprenavir and its salts and derivatives *Amprénavir et ses sels et dérivés*
	Amrinone and its salts *Amrinone et ses sels*
13-12-95	Amsacrine and its salts *Amsacrine et ses sels*
29-9-99	Anagrelide and its salts *Anagrélide et ses sels*
4-5-04	Anakinra and its salts and derivatives *Anakinra, ses sels et dérivés*
14-5-98	Anastrozole *Anastrozole*

14-11-00	Ancestim *Ancestim*
22-6-06	Anti-thymocyte globulin *Sérum antithymocytes*
	Apiol, oil of *Apiol (huile d')*
	Apraclonidine and its salts *Apraclonidine et ses sels*
	Aprotinin *Aprotinine*
18-6-03	Argatroban and its salts and derivatives *Argatroban, ses sels et dérivés*
	L-Asparaginase *L-Asparaginase*
4-12-97	Astemizole and its salts *Astémizole et ses sels*
21-9-06	Atazanavir and its salts *Atazanavir et ses sels*
	Atenolol and its salts *Aténolol et ses sels*
4-5-04	Atipamezole and its salts *Atipamézole et ses sels*
14-5-98	Atorvastatin and its salts *Atorvastatine et ses sels*
	Atovaquone *Atovaquone*
14-5-98	Atracurium besilate *Atracurium (bésilate d')*
	Atropine and its salts in ophthalmic or parenteral preparations only *Atropine et ses sels dans les préparations pour usage ophtalmique ou parentéral seulement*
	Auranofin *Auranofine*
	Aurothioglucose *Aurothioglucose*
	Azacyclonol and its salts *Azacyclonol et ses sels*
	Azaribine *Azaribine*
7-5-96	Azathioprine and its salts *Azathioprine et ses sels*
	Azatidine and its salts *Azatadine et ses sels*
	Azlocillin and its salts and derivatives *Azlocilline, ses sels et dérivés*
	Aztreonam and its salts *Aztréonam et ses sels*
	Baclofen and its salts *Baclofène et ses sels*
7-5-96	Bambuterol and its salts *Bambutérol et ses sels*
21-11-02	Basiliximab *Basiliximab*
18-5-00	Becaplermin *Bécaplermine*
	Bemegride *Bémégride*
	Benactyzine and its salts *Benactyzine et ses sels*
	Benazepril and its salts and derivatives *Bénazépril, ses sels et dérivés*

	Bendazac and its salts
	Bendazac et ses sels
	Benoxaprofen and its salts
	Benoxaprofène et ses sels
	Benserazide and its salts
	Bensérazide et ses sels
	Benzathine penicillin and its salts and derivatives
	Benzathine pénicilline, ses sels et dérivés
	Benzoyl peroxide in concentrations greater than 5 per cent or when sold in combination with another medicinal ingredient
	Benzoyle (peroxyde de) lorsqu'il constitue plus de cinq pour cent d'un mélange ou qu'il est vendu en association avec un autre ingrédient médicinal
	Benztropine and its salts
	Benzatropine et ses sels
	Benzydamine and its salts
13-12-95	*Benzydamine et ses sels*
	Beractant
	Béractant
	Betahistine and its salts
	Bétahistine et ses sels
29-9-99	Betaine and its salts when sold or recommended for the treatment of homocystinuria
	Bétaïne et ses sels s'ils sont vendus ou recommandés pour le traitement de l'homocystinurie
	Betaxolol and its salts
	Betaxolol et ses sels
	Bethanechol chloride
	Béthanéchol (chlorure de)
	Bethanidine and its salts
	Béthanidine et ses sels
	Bezafibrate and its salts and derivatives
	Bezafibrate, ses sels et dérivés
9-12-97	Bicalutamide
	Bicalutamide
4-5-04	Bimatoprost and its derivatives
	Bimatoprost et ses dérivés
	Biperiden and its salts
	Bipéridène et ses sels
	Bishydroxycoumarin and its salts and derivatives
	Bishydroxycoumarine, ses sels et dérivés
7-5-96	Bisoprolol and its salts
	Bisoprolol et ses sels
	Bitolterol and its salts
	Bitoltérol et ses sels
22-6-06	Bivalirudin
	Bivalirudine
	Bleomycin
	Bléomycine
21-9-06	Bortezomib
	Bortézomib
2-10-03	Bosentan and its salts and derivatives
	Bosentan et ses sels et dérivés
	Botulinum Toxin Type A
	Antitoxine botulinique, Type A
	Bretylium tosylate
	Brétylium (tosylate de)
29-9-99	Brimonidine and its salts
	Brimonidine et ses sels
	Bromal
	Bromal
	Bromal hydrate
	Bromal (hydrate de)
	Brometone
	Brométone
	Bromisoval
	Bromisoval

	Bromocriptine and its salts *Bromocriptine et ses sels*
	Bromoform *Bromoforme*
	Bumetanide and its salts and derivatives *Bumétanide, ses sels et dérivés*
4-5-04	Buproprion and its salts *Buproprione et ses sels*
	Buserelin and its salts *Busséréline et ses sels*
	Buspirone and its salts *Buspirone et ses sels*
	Busulfan *Busulfan*
	Butaperazine and its salts *Butapérazine et ses sels*
	Butoconazole and its salts *Butoconazole et ses sels*
	Butyl chloral hydrate *Butylchloral (hydrate de)*
21-11-02	Cabergoline and its salts *Cabergoline et ses sels*
	Calcipotriol *Calcipotriol*
	Calcitonin *Calcitonine*
	Calcitriol *Calcitriol*
	Calcium bromide *Bromure de calcium*
	Calcium bromolactobionate *Bromolactobionate de calcium*
	Calcium carbimide *Calcium (carbimide de)*
29-9-99	Candesartan and its salts and derivatives *Candésartan et ses sels et dérivés*
	Candicidin and its salts and derivatives *Candicidine, ses sels et dérivés*
29-9-99	Capecitabine and its salts and derivatives *Capécitabine et ses sels et dérivés*
	Capreomycin and its salts and deriviatives *Capréomycine, ses sels et dérivés*
	Captodiamine and its salts *Captodiamine et ses sels*
	Captopril and its salts *Captopril et ses sels*
	Carbachol *Carbachol*
	Carbamazepine *Carbamazépine*
	Carbenicillin and its salts and derviatives *Carbénicilline, ses sels et dérivés*
	Carbenoxolone and its salts *Carbenoxolone et ses sels*
29-9-99	Carbetocin and its salts *Carbétocine et ses sels*

	Carbidopa and its salts
	Carbidopa et ses sels
	Carbimazole
	Carbimazole
	Carbocisteine
	Carbocistéine
	Carbomycin and its salts and derivatives
	Carbomycine, ses sels et dérivés
	Carboplatin
	Carboplatine
	Carbromal
	Carbromal
	Carisoprodol
	Carisoprodol
	Carmustine
	Carmustine
	Carphenazine and its salts
	Carphénazine et ses sels
4-5-04	Carprofen and its salts and derivatives
	Carprofène, ses sels et dérivés
7-5-96	Carvedilol and its salts
	Carvédilol et ses sels
2-10-03	Caspofungin and its salts and derivatives
	Caspofungine et ses sels et dérivés
18-5-00	Cefdinir and its salts and derivatives
	Cefdinir et ses sels et dérivés
7-5-96	Cefepime and its salts and derivatives
	Céfépime, ses sels et dérivés
	Cefonicide and its salts
	Céfonicide et ses sels
	Cefoperazone and its salts and derivatives
	Céfopérazone, ses sels et dérivés
	Cefprozil and its salts and derivatives
7-5-96	*Cefprozil, ses sels et dérivés*
	Ceftibuten and its salts and derivatives
	Ceftibutène, ses sels et dérivés
	Celecoxib and its salts
	Célécoxib et ses sels
	Cephalosporin C and its salts and derivatives
	Céphalosporine C, ses sels et dérivés
29-9-99	Cerivastatin and its salts
	Cérivastatine et ses sels
	Cetirizine and its salts when sold in concentrations greater than 8.5 mg cetirizine per unit dose
	Cétirizine et ses sels lorsque vendues en concentration supérieure à 8,5 mg de cétirizine par unité posologique
31-5-05	Cetrorelix and its salts
	Cétrorélix et ses sels
	Chloral
	Chloral
	Chloral hydrate
	Chloral (hydrate de)
	Chloralformamide
	Chloralformamide
	Chloralimide
	Chloralimide
	Chlorambucil and its salts and derivatives
	Chlorambucil, ses sels et dérivés
13-12-95	Chloramphenicol and its salts and derivatives
	Chloramphénicol, ses sels et dérivés

	Chlorcyclizine and its salts (except in preparations for external use only) *Chlorcyclizine et ses sels (sauf dans les préparations pour usage externe seulement)*
	Chlorisondamine and its salts *Chlorisondamine et ses sels*
	Chlormezanone *Chlormézanone*
	Chloroquine and its salts *Chloroquine et ses sels*
	Chlorpropamide *Chlorpropamide*
	Chlorprothixene and its salts *Chlorprothixène et ses sels*
	Choline salicylate, when sold in combination with magnesium salicylate *Choline (salicylate de) s'il est vendu en association avec le salicylate de magnésium*
	Choline theophyllinate *Choline (théophyllinate de)*
	Ciclopirox and its salts *Ciclopirox et ses sels*
	Cilastatin and its salts *Cilastatine et ses sels*
	Cilazapril and its salts and derivatives *Cilazapril, ses sels et dérivés*
23-3-00	Cimetidine and its salts, except when sold in concentrations of 200 mg or less per oral dosage unit and indicated for the treatment of heartburn *Cimétidine et ses sels, sauf s'ils sont vendus en une concentration de 200 mg ou moins par unité posologique orale pour le traitement des brûlures d'estomac*
	Cinchophene and its salts *Cinchophène et ses sels*
	Cinoxacin *Cinoxacine*
	Ciprofloxacin and its salts *Ciprofloxacine et ses sels*
	Cisapride and its salts *Cisapride et ses sels*
14-5-98	Cisatracurium besilate *Cisatracurium (bésilate de)*
	Cisplatin *Cisplatine*
14-11-00	Citalopram and its salts *Citalopram et ses sels*
	Cladribine and its salts *Cladribine et ses sels*
	Clenbuterol and its salts *Clenbutérol et ses sels*
21-11-02	Clindamycin and its salts and derivatives *Clindamycine et ses sels et dérivés*
	Clodronic acid and its salts *Clodronique (acide) et ses sels*
13-12-95	Clofibrate *Clofibrate*
	Clomiphene and its salts *Clomiphène et ses sels*
	Clomipramine and its salts *Clomipramine et ses sels*
	Clonidine and its salts *Clonidine et ses sels*
29-9-99	Clopidogrel and its salts *Clopidogrel et ses sels*

	Cloprostenol and its salts and derivatives *Cloprosténol, ses sels et dérivés*
	Clorazepic acid and its salts *Clorazépique (acide) et ses sels*
	Clotrimazole and its salts (except in preparations for topical and vaginal use) *Clotrimazole et ses sels (sauf dans les préparations pour usage topique et vaginal)*
	Cloxacillin and its salts and derivatives *Cloxacilline, ses sels et dérivés*
	Clozapine and its salts *Clozapine et ses sels*
9-12-97	Colchicine *Colchicine*
	Colestipol and its salts *Colestipol et ses sels*
	Colfosceril and its derivatives *Colfoscéril et ses dérivés*
	Colistin and its salt and derivatives *Colistine, ses sels et dérivés*
15-5-98	Cromoglicic acid and its salts (except sodium cromoglicate in solutions for ophthalmic or nasal use in concentrations of 2% or less) *Cromoglicique (acide) et ses sels (sauf le cromoglicate de sodium dans les solutions pour usage ophtalmique ou nasal en concentration de 2 % ou moins)*
	Cyclobenzaprine and its salts *Cyclobenzaprine et ses sels*
	Cyclopentolate and its salts in preparations for parenteral or ophthalmic use, except when sold for use in diagnostic procedures to an optometrist registered in a province of Canada *Cyclopentolate et ses sels dans les préparations pour usage parentéral ou ophtalmique, sauf lorsqu'ils sont vendus pour usage diagnostique à un optométriste agréé dans une province du Canada*
	Cyclophosphamide *Cyclophosphamide*
	Cycloserine
13-12-95	*Cyclosérine*
	Cyclosporine *Cyclosporine*
	Cyproterone acetate *Cyprotérone (acétate de)*
	Cytarabine and its salts *Cytarabine et ses sels*
	Dacarbazine *Dacarbazine*
1-3-01	Daclizumab *Daclizumab*
	Dactinomycin *Dactinomycine*
6-12-01	Dalfopristin and its salts *Dalfopristine et ses sels*
	Dalteparin and its salts *Daltéparine et ses sels*
7-5-96	Danaparoid and its salts and derivatives *Danaparoïde, ses sels et dérivés*
	Danazol *Danazol*
21-9-06	Danofloxacin and its salts *Danofloxacine et ses sels*
	Dantrolene and its salts *Dantrolène et ses sels*

14-5-98	Dexfenfluramine and its salts *Dexfenfluramine et ses sels*
7-5-96	Dexrazoxane and its salts *Dexrazoxane et ses sels*
	Diazoxide and its salts *Diazoxide et ses sels*
	Dichloroacetic Acid *Dichloroacétique (acide)*
13-12-95	Diclofenac and its salts *Diclofénac et ses sels*
	Dicloxacillin and its salts and derivatives *Dicloxacilline, ses sels et dérivés*
	Didanosine and its salts and derivatives *Didanosine, ses sels et dérivés*
	Diethylbromacetamide *Diéthylbromacétamide*
	Diethylcarbamazine and its salts *Diéthylcarbamazine et ses sels*
	Diethylstilbestrol and its salts and derivatives *Diéthylstilbestrol, ses sels et dérivés*
21-11-02	Difloxacin and its salts and derivatives *Difloxacine et ses sels et dérivés*
	Diflunisal and its salts *Diflunisal et ses sels*
	Digitalis lanata and its glycosides *Digitalis lanata et ses glycosides*
	Digitalis purpurea and its glycosides *Digitalis purpurea et ses glycosides*
	Digoxin immune Fab (ovine) *Digoxine [Fragments d'anticorps spécifiques de la digoxine Fab (ovins)]*
	Dihydrotachysterol *Dihydrotachystérol*
	Diiodohydroxyquin (except in preparations for topical use on the skin) *Diiodohydroxyquinoléine (sauf dans les préparations pour usage topique sur la peau)*
	Diltiazem and its salts *Diltiazem et ses sels*
13-12-95	Dimercaprol *Dimercaprol*
14-5-98	Dimethyl sulfoxide *Diméthylsulfoxide*
	2,4-Dinitrophenol and its salts and derivatives *Dinitro-2,4-phénol, ses sels et dérivés*
	Dinoprostone and its salts and derivatives *Dinoprostone, ses sels et dérivés*
	Diphenidol and its salts *Diphénidol et ses sels*
	Diphenylhydantoin (phenytoin) and its salts *Diphénylhydantoine (phénytoïne) et ses sels*
	Dipivefrin and its salts *Dipivefrine et ses sels*
	Diprophylline and its salts *Diprophylline et ses sels*
	Dipyridamole *Dipyridamole*
	Disopyramide and its salts *Disopyramide et ses sels*
	Disulfiram *Disulfirame*
	Dobutamine and its salts *Dobutamine et ses sels*

9-12-97	Docetaxel and its derivatives *Docétaxel et ses dérivés*
14-5-98	Dolasetron and its salts *Dolasétron et ses sels*
	Domperidone *Dompéridone*
14-5-98	Donepezil and its salts *Donépézil et ses sels*
	Dopamine and its salts *Dopamine et ses sels*
7-5-96	Dornase alfa *Dornase alfa*
14-5-98	Dorzolamide and its salts *Dorzolamide et ses sels*
	Doxacurium chloride *Doxacurium (chlorure de)*
13-12-95	Doxapram *Doxapram*
	Doxazosin and its salts *Doxazosine et ses sels*
	Doxepin and its salts *Doxépine et ses sels*
2-10-03	Doxercalciferol and its derivatives *Doxercalciférol et ses dérivés*
	Doxorubicin and its salts *Doxorubicine et ses sels*
	Doxycycline and its salts and derivatives, when sold for intramuscular administration in caged birds *Doxycycline, ses sels et dérivés, lorsque vendue pour administration intramusculaire aux oiseaux en cage*
	Doxylamine and its salts, when sold or recommended for use in the nausea or vomiting of pregnancy *Doxylamine et ses sels lorsque vendus ou recommandés contre les nausées ou vomissements de la grossesse*
	Droperidol and its salts *Dropéridol et ses sels*
22-6-06	Drotrecogin *Drotrécogine*
22-6-06	Dutasteride *Dutastéride*
	Econazole and its salts *Éconazole et ses sels*
	Ecothiophate and its salts *Écothiophate et ses sels*
	Ectylurea and its salts *Ectylurée et ses sels*
	Edrophonium chloride *Édrophonium (chlorure d')*
18-5-00	Efavirenz *Éfavirenz*
18-6-03	Eflornithine and its salts and derivatives *Éflornithine, ses sels et dérivés*
	Embutramide *Embutramide*
29-9-99	Emedastine and its salts *Émédastine et ses sels*
	Emylcamate *Émylcamate*
	Enalaprilat and its salts and derivatives *Énalaprilate, ses sels et dérivés*
13-12-95	Enflurane *Enflurane*

22-6-06	Enfuvirtide
	Enfuvirtide
	Enoxaparin and its salts
	Énoxaparine et ses sels
	Enrofloxacin
	Enrofloxacine
18-6-03	Entacapone
	Entacapone
	Epirubicine and its salts
	Épirubicine et ses sels
14-5-98	Epoprostenol and its salts
	Époprosténol et ses sels
18-5-00	Epsiprantel
	Epsiprantel
14-11-00	Eprosartan and its salts and derivatives
	Éprosartan et ses sels et dérivés
14-11-00	Eptifibatide and its salts
	Eptifibatide et ses sels
22-6-06	Ertapenem and its salts
	Ertapénem et ses sels
	Erythropoietin
	Érythropoiétine
	Esmolol and its salts
	Esmolol et ses sels
2-10-03	Esomeprazole and its salts
	Ésoméprazole et ses sels
	Estramustine and its salts
	Estramustine et ses sels
18-6-03	Etanercept
	Étanercept
	Ethacrynic acid
	Étacrynique (acide)
	Ethambutol and its salts
	Éthambutol et ses sels
	Ethionamide and its salts
	Éthionamide et ses sels
	Ethomoxane and its salts
	Éthomoxane et ses sels
	Ethotoin and its salts
	Éthotoïne et ses sels
13-12-95	Ethyl trichloramate
	Éthyle (trichloramate d')
	Etidronic acid and its salts
	Étidronique (acide) et ses sels
7-5-96	Etodolac and its salts and derivatives
	Étodolac, ses sels et dérivés
14-5-98	Etoposide and its derivatives
	Étoposide et ses dérivés
	Etretinate
	Étrétinate
	Etymemazine and its salts
	Étymémazine et ses sels
21-11-02	Exemestane
	Exémestane
22-6-06	Ezetimibe
	Ézétimibe

9-12-97	Famciclovir and its salts *Famciclovir et ses sels*
20-6-96	Famotidine and its salts (except in preparations for oral use containing 10 mg or less of famotidine per dosage unit) *Famotidine et ses sels (sauf dans les préparations pour usage oral contenant 10 mg ou moins de famotidine par unité posologique)*
	Felodipine and its salts *Félodipine et ses sels*
	Fenfluramine and its salts *Fenfluramine et ses sels*
	Fenofibrate *Fénofibrate*
	Fenoprofen and its salts *Fénoprofène et ses sels*
	Fenoterol and its salts *Fénotérol et ses sels*
	Filgrastim *Filgrastime*
13-12-95	Finasteride *Finastéride*
	Flavoxate and its salts *Flavoxate et ses sels*
	Flecainide and its salts *Flécaïnide et ses sels*
14-5-98	Fleroxacin and its salts and derivatives *Fléroxacine, ses sels et dérivés*
	Floctafenine *Floctafénine*
14-5-98	Florfenicol and its derivatives *Florfénicol et ses dérivés*
	Fluconazole *Fluconazole*
	Flucytosine *Flucytosine*
	Fludarabine and its salts and derivatives *Fludarabine, ses sels et dérivés*
	Flunarizine and its salts *Flunarizine et ses sels*
	Flunixin and its salts and derivatives *Flunixine, ses sels et dérivés*
	Fluorouracil and its derivatives *Fluorouracile et ses dérivés*
	Fluoxetine and its salts *Fluoxétine et ses sels*
	Flupentixol and its salts and derivatives *Flupentixol, ses sels et dérivés*
	Fluphenazine and its salts *Fluphénazine et ses sels*
	Fluprostenol and its salts and derivatives *Fluprosténol, ses sels et dérivés*
	Flurbiprofen and its salts *Flurbiprofène et ses sels*
13-12-95	Fluspirilene *Fluspirilène*
	Flutamide *Flutamide*
	Fluvastatin and its salts and derivatives *Fluvastatine, ses sels et dérivés*
	Fluvoxamine and its salts *Fluvoxamine et ses sels*

4-12-97	Folic acid in oral dosage form containing more than 1.0 mg of folic acid per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by that person or more than 1.0 mg of folic acid *Acide folique présenté en unités posologiques orales contenant chacune plus de 1,0 mg d'acide folique ou dont la plus forte dose quotidienne recommandée sur l'étiquette résulte en l'ingestion, par une personne, de plus de 1,0 mg d'acide folique*
29-9-99	Follicle stimulating hormone *Folliculo-stimulante (hormone)*
18-6-03	Fomepizole and its salts *Fomépizole et ses sels*
22-6-06	Fondaparinux sodium *Fondaparinux sodique*
7-5-96	Formestane and its derivatives *Formestane et ses dérivés*
22-6-06	Formoterol and its salts *Formotérol et ses sels*
	Foscarnet sodium *Foscarnet sodique*
29-9-99	Fosfomycin and its salts *Fosfomycine et ses sels*
	Fosinopril and its salts *Fosinopril et ses sels*
14-5-98	Fosphenytoin and its salts *Fosphénytoïne et ses sels*
21-9-06	Fulvestrant *Fulvestrant*
	Fusidic acid and its salts *Fusidique (acide) et ses sels*
7-5-96	Gabapentin and its salts and derivatives *Gabapentin, ses sels et dérivés*
	Gallamine triethiodide *Gallamine (triéthiodure de)*
	Gallium and its salts *Gallium et ses sels*
2-10-03	Galantamine and its salts and derivatives *Galantamine et ses sels et dérivés*
	Ganciclovir and its salts *Ganciclovir et ses sels*
4-5-04	Ganirelix and its salts and derivatives *Ganirélix, ses sels et dérivés*
18-6-03	Gatifloxacin and its salts and derivatives *Gatifloxacine, ses sels et dérivés*
21-9-06	Gefitinib *Géfitinib*
14-5-98	Gemcitabine and its salts *Gemcitabine et ses sels*
	Gemfibrozil and its salts *Gemfibrozil et ses sels*
21-9-06	Gemifloxacin and its salts *Gémifloxacine et ses sels*
	Gentamicin and its salts and derivatives *Gentamicine, ses sels et dérivés*
14-5-98	Glatiramer and its salts *Glatiramère et ses sels*
	Gliclazide *Gliclazide*
4-5-04	Glimepiride *Glimépiride*
	Glipizide
13-12-95	*Glipizide*

	Glyburide and its salts and derivatives *Glyburide, ses sels et dérivés*
	Gold and its salts *Or et ses sels*
	Gonadorelin and its salts *Gonadoréline et ses sels*
	Gonadotropin, chorionic (human) *Gonadotropine chorionique (humain)*
	Gonadotropins, serum (human) *Gonadotropines sériques (humains)*
	Goserelin and its salts *Gosséréline et ses sels*
7-5-96	Granisetron and its salts *Granisetron et ses sels*
29-9-99	Grepafloxacin and its salts and derivatives *Grépafloxacine et ses sels et dérivés*
	Guanethidine and its salts *Guanéthidine et ses sels*
7-5-96	Halofantrine and its salts *Halofantrine et ses sels*
	Haloperidol *Halopéridol*
	Halothane *Halothane*
	Hetacillin and its salts and derivatives *Hétacilline, ses sels et dérivés*
21-9-06	Hetastarch and its derivatives *Hetastarch et ses dérivés*
	Hexachlorophene and its salts *Hexachlorophène et ses sels*
	Hexacyclonate sodium *Hexacyclonate sodique*
	Hexamethonium and its salts *Hexaméthonium et ses sels*
	Hyaluronic acid and its salts, when sold or recommended for administration by intra-articular injection to horses *Hyaluronique (acide) et ses sels, s'il est vendu ou recommandé pour administration par injection intra-articulaire aux chevaux*
	Hydralazine and its salts *Hydralazine et ses sels*
	Hydroxychloroquine and its salts *Hydroxychloroquine et ses sels*
	4-Hydroxycoumarin and its derivatives when sold or recommended as anticoagulants *Hydroxy-4 coumarine et ses dérivés, s'ils sont vendus ou recommandés comme anticoagulants*
	Hydroxyurea *Hydroxyurée*
	Hydroxyzine and its salts and derivatives *Hydroxyzine, ses sels et dérivés*
21-9-06	Ibandronic acid and its salts *Acide ibandronique et ses sels*
21-11-02	Ibutilide and its salts and derivatives *Ibutilide et ses sels et dérivés*
31-1-02	Ibuprofen and its salts except when sold for oral administration in a concentration of 400 mg or less per dosage unit. *Ibuprofène et ses sels, sauf s'ils sont vendus pour administration par voie orale en une concentration de 400 mg ou moins par unité posologique*

	Idarubicin and its salts *Idarubicine et ses sels*
	Idoxuridine *Idoxuridine*
	Ifosfamide *Ifosfamide*
2-10-03	Imatinib and its salts *Imatinib et ses sels*
14-5-98	Imiglucerase *Imiglucérase*
	Imipenem and its salts and derivatives *Imipénem, ses sels et dériwés*
	Imipramine and its salts *Imipramine et ses sels*
18-5-00	Imiquimod and its salts *Imiquimod et ses sels*
	Indapamide and its salts *Indapamide et ses sels*
14-5-98	Indinavir and its salts *Indinavir et ses sels*
	Indomethacin *Indométhacine*
18-6-03	Infliximab *Infliximab*
	Inosiplex *Inosiplex*
	Interferon *Interféron*
	Iodochlorohydroxyquin (except in preparations for topical use on the skin) *Iodochlorhydroxyquinoléine (sauf dans les préparations pour usage topique sur la peau)*
	Ipratropium and its salts *Ipratropium et ses sels*
	Iproniazid and its salts *Iproniazide et ses sels*
29-9-99	Irbesartan and its salts *Irbésartan et ses sels*
14-5-98	Irinotecan and its salts *Irinotécan et ses sels*
	Isocarboxazid and its salts *Isocarboxazide et ses sels*
	Isoflurane *Isoflurane*
	Isoniazid *Isoniazide*
	Isoproterenol (Isoprenaline) and its salts *Isoprotérénol (Isoprénaline) et ses sels*
	Isotretinoin and its salts *Isotrétinoïne et ses sels*
	Isoxsuprine and its salts *Isoxsuprine et ses sels*
	Isradipine and its salts *Isradipine et ses sels*
	Itraconazole and its salts *Itraconazole et ses sels*
4-5-04	Ivermectin and its derivatives, for human use or for veterinary use when sold for intramuscular injection into horses or for oral administration to dogs and cats *Ivermectine et ses dérivés, destinés à l'usage humain ou à l'usage vétérinaire, s'ils sont vendus pour injection intramusculaire aux chevaux ou pour administration par voie orale aux chiens et aux chats*
31-8-05	Repealed by P.C. 2005-1518 of August 31, 2005.

31-5-05	Ketanserin and its salts *Kétansérine et ses sels*
	Ketoconazole and its salts (except in preparations for topical use as a shampoo) *Kétoconazole et ses sels (excepté pour les préparations pour usage topique sous la forme d'un shampooing)*
	Ketoprofene and its salts *Kétoprofène et ses sels*
	Ketorolac and its salts *Kétorolac et ses sels*
	Ketotifen and its salts *Kétotifène et ses sels*
	Labetalol and its salts *Labétalol et ses sels*
	Lactic acid, when recommended for parenteral use as a tissue sclerosing agent *Acide lactique, s'il est recommandé pour usage parentéral comme agent sclérosant*
9-12-97	Lamivudine and its salts *Lamivudine et ses sels*
	Lamotrigine and its salts
7-5-96	*Lamotrigue et ses sels*
	Lansoprazole and its salts *Lansoprazole et ses sels*
14-5-98	Latanoprost *Latanoprost*
6-12-01	Leflunomide and its salts *Léflunomide et ses sels*
14-5-98	Letrozole *Létrozole*
	Leucovorin and its salts *Acide folinique et ses sels*
	Leuprolide and its salts *Leuproréline et ses sels*
22-6-06	Levetiracetam *Lévétiracétam*
	Levobunolol and its salts *Levobunolol et ses sels*
	Levocabastine and its salts and derivatives
13-12-95	*Lévocabastine, ses sels et dérivés*
	Levocarnitine and its salts and derivatives
9-12-97	*Lévocarnitine et ses sels et dérivés*
	Levodopa and its salts *Lévodopa et ses sels*
18-6-03	Linezolid and its salts *Linézolide et ses sels*
	Lisinopril and its salts and derivatives *Lisinopril, ses sels et dérivés*
	Lithium and its salts *Lithium et ses sels*
	Lodoxamide and its salts and derivatives *Lodoxamide, ses sels et dérivés*
	Lomefloxacin and its salts *Loméfloxacine et ses sels*
	Lomustine *Lomustine*
18-6-03	Lopinavir *Lopinavir*
	Loracarbef and its salts and derivatives *Loracarbef, ses sels et dérives*
9-12-97	Losartan and its salts *Losartan et ses sels*

7-5-96	Losoxantrone and its salts *Losoxantrone et ses sels*
	Lovastatin *Lovastatine*
	Loxapine and its salts *Loxapine et ses sels*
	Magnesium glutamate hydrobromide *Bromhydrate de glutamate de magnésium*
	Maprotiline and its salts *Maprotiline et ses sels*
1-3-01	Marbofloxacin and its salts and derivatives *Marbofloxacine et ses sels et dérivés*
	Mecamylamine and its salts *Mécamylamine et ses sels*
	Mechlorethamine and its salts *Méchloréthamine et ses sels*
	Mecillinam and its salts and derivatives *Mécillinam, ses sels et dérivés*
	Meclofenamic acid and its salts *Méclofénamique (acide) et ses sels*
4-5-04	Medetomidine and its salts *Médétomidine et ses sels*
13-12-95	Mefenamic acid and its salts *Méfénamique (acide) et ses sels*
	Mefloquine and its salts and derivatives *Méfloquine, ses sels et dérivés*
	Megestrol and its salts *Mégestrol et ses sels*
1-3-01	Melanoma therapeutic vaccine *Vaccin thérapeutique contre le mélanome*
4-5-04	Melarsomine and its salts, when sold for the treatment of heartworm in dogs *Mélarsomine et ses sels, s'ils sont vendus pour le traitement du ver du coeur chez le chien*
2-10-03	Meloxicam and its salts and derivatives *Méloxicam et ses sels et dérivés*
	Melphalan *Melphalan*
21-9-06	Memantine and its salts *Mémantine et ses sels*
	Menotropins (human) *Ménotropines (humains)*
	Mepacrine and its salts *Mépacrine et ses sels*
	Mepazine and its salts *Mépazine et ses sels*
	Mephenoxalone *Méphenoxalone*
	Mephentermine and its salts *Méphentermine et ses sels*
	Mercaptopurine *Mercaptopurine*
14-5-98	Meropenem and its salts and derivatives *Méropénem, ses sels et dérivés*
	Mesna *Mesna*
	Mesoridazine and its salts *Mésoridazine et ses sels*
	Metaldehyde *Métaldéhyde*

	Metformin and its salts and derivatives
	Metformine, ses sels et dérivés
14-11-00	Methacholine chloride
	Méthacholine (chlorure de)
18-5-00	Methazolamide and its salts
	Méthazolamide et ses sels
	Methicillin and its salts and derivatives
	Méthicilline, ses sels et dérivés
	Methimazole
	Méthimazole
	Methisazone
	Méthisazone
	Methoin (Mephenytoin) and its salts
	Méthoïne (méphénytoïne) et ses sels
	Methotrexate and its salts
	Méthotrexate et ses sels
	Methotrimeprazine and its salts
	Méthotriméprazine et ses sels
	Methoxamine and its salts
	Méthoxamine et ses sels
14-5-98	Methoxsalen
	Méthoxsalène
	Methyldopa and its salts
	Méthyldopa et ses sels
	Methylparafynol
13-12-95	*Méthylparafynol*
	Methysergide and its salts and derivatives
	Méthysergide, ses sels et dérivés
	Metoclopramide
	Métoclopramide
	Metolazone and its salts
	Métolazone et ses sels
	Metomidate and its salts
	Métomidate et ses sels
	Metopimazine and its salts
	Métopimazine et ses sels
22-6-06	Metoprolol and its salts
	Métoprolol et ses sels
	Metronidazole
	Métronidazole
	Metyrapone and its salts
	Métyrapone et ses sels
	Mexiletine and its salts
	Mésiletine et ses sels
	Mezlocillin and its salts and derivatives
	Mézlocilline, ses sels et dérivés
	Miconazole and its salts (except in preparations for topical and vaginal use)
	Miconazole et ses sels (sauf dans les préparations pour usage topique et vaginal)
	Midodrine and its salts
	Midodrine et ses sels
	Milbemycin and its derivatives
	Milbémycine et ses dérivés
	Milrinone and its salts
	Milrinone et ses sels
21-10-99	Minoxidil (except in solutions for topical use in concentrations of 2% or less)
	Minoxidil (sauf dans les solutions pour usage topique où sa concentration est de 2 % ou moins)
2-10-03	Mirtazapine and its salts
	Mirtazapine et ses sels
	Mitomycin and its salts
	Mitomycine et ses sels
	Mitotane (o,p'-DDD)
	Mitotane (o,p'-DDD)

	Mitoxantrone and its salts *Mitoxantrone et ses sels*
7-5-96	Mivacurium chloride *Mivacurium (chlorure de)*
21-9-06	Modafinil and its salts *Modafinil et ses sels*
14-5-98	Molgramostim *Molgramostim*
29-9-99	Montelukast and its salts *Montélukast et ses sels*
4-5-04	Moxidectin and its derivatives, when sold for the prevention of heartworm in dogs *Moxidectine et ses dérivés, s'ils sont vendus pour la prévention du ver du coeur chez le chien*
18-6-03	Moxifloxacin and its salts and derivatives *Moxifloxacine, ses sels et dérivés*
9-12-97	Mycophenolic acid and its salts and derivaties *Mycophénolique (acide) et ses sels et dérivés*
7-5-96	Nabumetone *Nabumétone*
	Nadolol and its salts *Nadolol et ses sels*
29-9-99	Nadroparin and its salts *Nadroparine et ses sels*
	Nafarelin and its salts and derivatives *Nafaréline, ses sels et dérivés*
	Nafcillin and its salts and derivatives *Nafcilline, ses sels et dérivés*
	Nalidixic acid *Nalidixique (acide)*
29-9-99	Nalmefene and its salts *Nalméfène et ses sels*
13-12-95	Naloxone and its salts *Naloxone et ses sels*
7-5-96	Naltrexone and its salts *Naltrexone et ses sels*
	Naproxen and its salts *Naproxène et ses sels*
29-9-99	Naratriptan and its salts *Naratriptan et ses sels*
2-10-03	Nateglinide and its salts and derivatives *Natéglinide et ses sels et dérivés*
	Nedocromil and its salts *Nédocromil et ses sels*
7-5-96	Nefazodone and its salts *Néfazodone et ses sels*
29-9-99	Nelfinavir and its salts *Nelfinavir et ses sels*
	Neocinchophen and its salts *Néocinchophène et ses sels*
	Neostigmine salts *Néostigmine (les sels de)*
	Netilmicin and its salts and derivatives *Nétilmicine, ses sels et dérivés*
18-5-00	Nevirapine and its salts *Névirapine et ses sels*
	Nialamide and its salts
13-12-95	*Nialamide et ses sels*
	Nicardipine and its salts *Nicardipine et ses sels*

Nicotine and its salts, for human use, except
(a) in natural substances;
(b) in the form of a chewing gum containing 4 mg or less of nicotine per dosage unit;
(c) in the form of a transdermal patch with a delivery rate of 22 mg or less of nicotine per day;
(d) in a form to be administered orally by means of an inhalation device delivering 4 mg or less of nicotine per dosage unit; or
22-6-06 (e) in the form of a lozenge containing 4 mg or less of nicotine per dosage unit

Nicotine et ses sels, destinés à l'usage humain, sauf :
(a) dans les substances naturelles;
(b) sous forme de gomme à mâcher contenant 4 mg ou moins de nicotine par unité posologique;
(c) sous forme de timbre cutané ayant un taux de libération de 22 mg ou moins de nicotine par jour;
(d) sous une forme destinée à être administrée par voie orale au moyen d'un inhalateur libérant 4 mg ou moins de nicotine par unité posologique;
(e) sous forme de pastille contenant 4 mg ou moins de nicotine par unité posologique

Nifedipine
Nifédipine

Nilutamide
Nilutamide

Nimodipine and its salts
Nimodipine et ses sels

18-5-00 Nitroscanate
Nitroscanate

14-5-98 Nizatidine and its salts (except when sold in an oral dosage form containing not more than the equivalent of 75 mg of nizatidine)
Nizatidine et ses sels (sauf lorsque vendue sous une forme posologique orale contenant au plus l'équivalent de 75 mg de nizatidine)

Nomifensine and its salts
Nomifensine et ses sels

Norfloxacin
Norfloxacine

Nortriptyline and its salts
Nortriptyline et ses sels

Nylidrin and its salts
Nylidrine et ses sels

	Octatropine methylbromide
	Octatropine (méthylbromure d')
	Octreotide
	Octréotide
	Ofloxacin and its salts
	Ofloxacine et ses sels
29-9-99	Olanzapine and its salts
	Olanzapine et ses sels
14-5-98	Olopatadine and its salts
	Olopatadine et ses sels
	Olsalazine and its salts
	Olsalazine et ses sels
4-5-04	Omeprazole and its salts
	Oméprazole et ses sels
	Ondansetron and its salts
	Ondansétron et ses sels
4-5-04	Orbifloxacin and its salts and derivatives
	Orbifloxacine, ses sels et dérivés
	Orciprenaline (Metaproterenol) and its salts
	Orciprénaline (Métaprotérénol) et ses sels
14-11-00	Orlistat
	Orlistat
	Ormetoprim and its salts
	Ormétoprime et ses sels
13-12-95	Ornidazole
	Ornidazole
1-3-01	Oseltamivir and its salts
	Oséltamivir et ses sels
	Oxacillin, and its salts and derivatives
	Oxacilline, ses sels et dérivés
	Oxanamide
	Oxanamide
	Oxaprozin and its salts and derivatives
	Oxaprozine, ses sels et dérivés
6-12-01	Oxcarbazepine
	Oxcarbazépine
	Oxolinic acid and its salts
	Oxolinique (acide) et ses sels
	Oxprenolol and its salts
	Oxprénolol et ses sels
	Oxybutynin and its salts
	Oxybutynine et ses sels
	Oxyphenbutazone and its salts
	Oxyphenbutazone et ses sels
	Oxytocin
	Oxytocine

	Paclitaxel and its derivatives *Paclitaxel et ses dérivés*
4-5-04	Palivizumab *Palivizumab*
	Pamidronic acid and its salts *Pamidronique (acide) et ses sels*
	Pancuronium and its salts *Pancuronium et ses sels*
14-5-98	Pantoprazole and its salts *Pantoprazole et ses sels*
	Paraldehyde *Paraldéhyde*
	Paramethadione *Paraméthadione*
13-12-95	Pargyline and its salts *Pargyline et ses sels*
	Paroxetine and its salts *Paroxétine et ses sels*
18-5-00	Penciclovir and its salts *Penciclovir et ses sels*
	Penicillamine *Pénicillamine*
	Pentamidine and its salts *Pentamidine et ses sels*
	Pentolinium tartrate *Pentolinium (tartrate de)*
7-5-96	Pentosan polysulfate and its salts *Pentosane polysulfate et ses sels*
	Pentostatin and its salts *Pentostatine et ses sels*
	Pentoxifylline and its salts *Pentoxifylline et ses sels*
18-6-03	Perflutren *Perflutrène*
	Pergolide and its salts *Pergolide et ses sels*
	Pericyazine and its salts *Péricyazine et ses sels*
7-5-96	Perindopril and its salts *Périndopril et ses sels*
	Perphenazine and its salts *Perphénazine et ses sels*
	Phacetoperane and its salts *Phacétopérane et ses sels*
	Phenacemide *Phénacémide*
	Phenacetin *Phénacétine*
	Phenaglycodol *Phénaglycodol*
	Phenazopyridine and its salts *Phénazopyridine et ses sels*
13-12-95	Phenelzine and its salts *Phénelzine et ses sels*
	Phenformin and its salts *Phenformine et ses sels*
	Pheniprazine and its salts *Phéniprazine et ses sels*

	Phenthoxate and its salts *Phentoxate et ses sels*
	Phentolamine and its salts *Phentolamine et ses sels*
	Phenylbutazone and its salts *Phénylbutazone et ses sels*
	Phenylephrine and its salts in preparations for ophthalmic or parenteral use in concentrations greater than 2.5% *Phényléphrine et ses sels dans les préparations pour usage ophtalmique ou parentéral lorsqu'il constitue plus de 2,5% d'un mélange*
	Phenylindanedione and its derivatives *Phénylindanédione et ses dérivés*
31-5-05	Phenylpropanolamine and its salts and derivatives for veterinary use *Phénylpropanolamine, ses sels et dérivés, destinés à l'usage vétérinaire*
14-5-98	Pilocarpine and its salts *Pilocarpine et ses sels*
22-6-06	Pimecrolimus *Pimécrolimus*
	Pimozide *Pimozide*
14-5-98	Pinaverium bromide *Pinavérium (bromure de)*
	Pindolol and its salts *Pindolol et ses sels*
2-10-03	Pioglitazone and its salts
21-11-02	*Pioglitazone et ses sels*
	Pipecuronium bromide *Pipécuronium (bromure de)*
	Piperacetazine and its salts *Pipéracétazine et ses sels*
	Piperilate and its salts *Pipérilate et ses sels*
	Pipotiazine and its salts *Pipotiazine et ses sels*
	Pipobroman *Pipobroman*
	Pirbuterol and its salts *Pirbutérol et ses sels*
	Pirenzepine and its salts *Pirenzépine et ses sels*
	Piroxicam and its salts *Piroxicam et ses sels*
	Pizotyline and its salts *Pizotyline et ses sels*
13-12-95	Podophyllum and the following extracts and active principles, when sold or recommended for topical use: (a) podophyllotoxin (b) podophyllum resin *Podophyllum, ses extraits et principes actifs suivants lorsque vendus ou recommandés pour usage topique:* *a) podophyllotoxine* *b) podophyllum (résine de)*
	Polysulfated glycosaminoglycan *Glycosaminoglycan polysulfaté*
21-9-06	Ponazuril *Ponazuril*
1-3-01	Poractant alfa *Poractant alfa*
	Porfimer and its salts *Porfimère et ses sels*
	Potassium bromide *Bromure de potassium*
14-5-98	Potassium gluconate, when sold or recommended for administration to cats *Potassium (gluconate de), lorsqu'il est vendu ou recommandé pour administration aux chats*

	Potassium para-aminobenzoate (except in preparations for topical use on the skin) *Potassium (para-aminobenzoate de) (sauf dans les préparations pour usage topique sur la peau)*
	Pralidoxime and its salts *Pralidoxime et ses sels*
29-9-99	Pramipexole and its salts *Pramipexole et ses sels*
	Pravastatin and its salts *Pravastatine et ses sels*
4-5-04	Praziquantel, except when sold for the treatment of the tapeworm Anoplocephala perfoliata in horses *Praziquantel, sauf s'il est vendu pour le traitement du ver solitaire Anoplocephala perfoliata chez les chevaux*
	Prazosin and its salts *Prazosine et ses sels*
	Prenylamine and its salts *Prénylamine et ses sels*
	Primaquine and its salts *Primaquine et ses sels*
	Probenecid and its salts *Probénécide et ses sels*
	Probucol *Probucol*
	Procainamide and its salts *Procainamide et ses sels*
	Procarbazine and its salts *Procarbazine et ses sels*
	Procaterol and its salts *Procatérol et ses sels*
	Prochlorperazine and its salts *Prochlorpérazine et ses sels*
	Procyclidine and its salts *Procyclidine et ses sels*
	Prodilidine and its salts *Prodilidine et ses sels*
	Profenamine and its salts *Profénamine et ses sels*
	Proguanil and its salts *Proguanil et ses sels*
	Propafenone and its salts *Propafénone et ses sels*
9-12-97	Propofol *Propofol*
	Propranolol and its salts *Propranolol et ses sels*
	Prostaglandins and their salts and derivatives *Prostaglandines, leurs sels et dérivés*
	Prothipendyl hydrochloride *Prothipendyl (chlorhydrate de)*
	Protirelin
13-12-95	*Protireline*
	Protriptyline and its salts *Protriptyline et ses sels*
	Pyrazinamide *Pyrazinamide*
	Pyridostigmine bromide *Pyridostigmine (bromure de)*
	Pyrimethamine and its salts *Pyriméthamine et ses sels*

29-9-99	Quetiapine and its salts *Quétiapine et ses sels*
14-5-98	Quinagolide and its salts *Quinagolide et ses sels*
	Quinapril and its salts and derivatives *Quinapril, ses sels et dérivés*
6-12-01	Quinupristin and its salts *Quinupristine et ses sels*
18-6-03	Rabeprazole and its salts *Rabéprazole et ses sels*
29-9-99	Raloxifene and its salts *Raloxifène et ses sels*
14-5-98	Raltitrexed and its salts and derivatives *Raltitrexed, ses sels et dérivés*
	Ramipril and its salts and derivatives *Ramipril, ses sels et dérivés*
28-8-97	Ranitidine and its salts (except when sold in a dosage form containing not more than the equivalent of 75 mg of ranitidine) *Ranitidine et ses sels (sauf lorsque vendue sous une forme posologique contenant au plus l'équivalent de 75 mg de ranitidine*
	Raubasine and its salts *Raubasine et ses sels*
	Rauwolfia *Rauwolfia*
	Remoxipride and its salts *Rémoxipride et ses sels*
18-5-00	Repaglinide and its salts and derivatives *Répaglinide et ses sels et dérivés*
	Rescinnamine and its salts *Rescinnamine et ses sels*
14-5-98	Reviparin and its salts *Réviparine et ses sels*
	Ribavirin *Ribavirine*
	Rifabutin and its salts *Rifabutine et ses sels*
	Rifampin and its salts and derivatives *Rifampine, ses sels et dérivés*
21-11-02	Riluzole and its salts *Riluzole et ses sels*
1-3-01	Risedronic acid and its salts *Acide risédronique et ses sels*
	Risperidone and its salts *Rispéridone et ses sels*
	Ritodrine and its salts *Ritodrine et ses sels*
14-5-98	Ritonavir *Ritonavir*
6-12-01	Rituximab *Rituximab*
29-9-99	Rivastigmine and its salts *Rivastigmine et ses sels*
14-11-00	Rizatriptan and its salts *Rizatriptan et ses sels*
7-5-96	Rocuronium bromide *Rocuronium (bromure de)*

1-3-01	Rofecoxib *Rofécoxib*
4-5-04	Romifidine and its salts *Romifidine et ses sels*
14-5-98	Ropinirole and its salts *Ropinirole et ses sels*
6-12-01	Rosiglitazone and its salts *Rosiglitazone et ses sels*
	Rosoxacin and its salts *Rosoxacine et ses sels*
22-6-06	Rosuvastatin and its salts *Rosuvastatine et ses sels*
	Salbutamol and its salts *Salbutamol et ses sels*
7-5-96	Salmeterol and its salts *Salmetérol et ses sels*
	Salsalate and its salts and derivatives *Salsalate, ses sels et dérivés*
14-5-98	Saquinavir and its salts and derivatives *Saquinavir, ses sels et dérivés*
	Saralasin and its salts *Saralasine et ses sels*
7-5-96	Sargramostim *Sargramostim*
	Selegiline and its salts *Sélégiline et ses sels*
9-12-97	Sermorelin and its salts *Sermoréline et ses sels*
	Sertraline and its salts *Sertraline et ses sels*
6-12-01	Sevelamer and its salts *Sévélamer et ses sels*
21-9-06	Sibutramine and its salts *Sibutramine et ses sels*
18-5-00	Sildenafil and its salts *Sildénafil et ses sels*
	Simvastatin *Simvastatine*
18-6-03	Sirolimus and its derivatives *Sirolimus et ses dérivés*
	Sodium aurothiomalate *Aurothiomalate de sodium*
	Sodium bromide *Bromure de sodium*
	Sodium nitroprusside and its salts *Sodium (nitroprussiate de) et ses sels*
	Sodium polystyrene sulfonate *Sulfonate de polystyrène de sodium*
7-5-96	Somatostatin *Somatostatine*
	Somatrem *Somatrem*
	Somatropin *Somatropine*
	Sotalol and its salts *Sotalol et ses sels*
9-12-97	Spironolactone *Spironolactone*
14-5-98	Stavudine *Stavudine*

	Streptozocin
	Streptozocine
	Strontium bromide
	Bromure de strontium
13-12-95	Succinimide and its salts and derivatives (except those compounds used for decontaminating water)
	Succinimide, ses sels et dérivés (sauf les produits utilisés pour décontaminer l'eau)
	Sucralfate
	Sucralfate
	Sulconazole and its salts
	Sulconazole et ses sels
	Sulfinpyrazone and its salts
	Sulfinpyrazone et ses sels
	Sulindac and its salts
	Sulindac et ses sels
	Sulphones and their derivatives
	Sulphones et leurs dérivés
	Sumatriptan and its salts
	Sumatriptan et ses sels
7-5-96	Suprofen and its salts
	Suprofène et ses sels
	Suxamethonium chloride
	Suxaméthonium (chlorure de)
9-12-97	Tacrolimus and its derivatives
	Tacrolimus et ses dérivés
31-5-05	Tadalafil and its salts
	Tadalafil et ses sels
	Tamoxifen and its salts
	Tamoxifène et ses sels
29-9-99	Tamsulosin and its salts
	Tamsulosine et ses sels
14-5-98	Tazarotene
	Tazarotène
7-5-96	Tazobactam and its salts and derivatives
	Tazobactam, ses sels et dérivés
31-5-05	Teflubenzuron
	Teflubenzuron
18-6-03	Tegafur and its salts
	Tégafur et ses sels
4-5-04	Tegaserod and its salts
	Tégasérod et ses sels
22-6-06	Telithromycin and its salts and derivatives
	Télithromycine et ses sels et dérivés
1-3-01	Telmisartan and its salts and derivatives
	Telmisartan et ses sels et dérivés
1-3-01	Temozolomide and its salts
	Témozolomide et ses sels
2-10-03	Tenecteplase and its salts and derivatives
	Ténectéplase et ses sels et dérivés
	Teniposide
	Téniposide
22-6-06	Tenofovir and its salts and derivatives
	Ténofovir et ses sels et dérivés
	Tenoxicam and its salts
	Ténoxicam et ses sels
	Terazosin and its salts
	Térazosine et ses sels
	Terbinafine and its salts
	Terbinafine et ses sels

	Terbutaline and its salts *Terbutaline et ses sels*
	Terconazole and its salts *Terconazole et ses sels*
4-12-97	Terfenadine and its salts *Terfénadine et ses sels*
	Terlipressin and its salts *Terlipressine et ses sels*
9-12-97	Tetrabenazine and its salts *Tétrabénazine et ses sels*
	Thalidomide *Thalidomide*
	Theobromine and its salts
13-12-95	*Théobromine et ses sels*
	Theophylline and its salts *Théophylline et ses sels*
	Thiethylperazine and its salts *Thiéthylpérazine et ses sels*
	Thiocarlide *Thiocarlide*
	Thioguanine *Thioguanine*
	Thiopropazate and its salts *Thiopropazate et ses sels*
	Thioproperazine and its salts *Thiopropérazine et ses sels*
	Thioridazine and its salts *Thioridazine et ses sels*
	Thiotepa *Thiotépa*
	Thiothixene and its salts *Thiothixène et ses sels*
	Thiouracil and its derivatives *Thiouracile et ses dérivés*
4-5-04	Thyrotropin alfa *Thyrotropine alfa*
	Thyroxin and its salts *Thyroxine et ses sels*
	Tiaprofenic acid and its salts *Tiaprofénique (acide) et ses sels*
	Ticarcillin and its salts and derivatives *Ticarcilline, ses sels et dérivés*
	Ticlopidine and its salts *Ticlopidine et ses sels*
14-11-00	Tilmicosin, except in preparations for veterinary use to be administered orally *Tilmicosine, sauf dans les préparations pour usage vétérinaire destinées à être administrées par voie orale*
14-5-98	Tiludronic acid and its salts *Tiludronique (acide) et ses sels*
	Timolol and its salts *Timolol et ses sels*
13-12-95	Tinidazole *Tinidazole*
	Tinzaparin and its salts *Tinzaparine et ses sels*
	Tioconazole and its salts (except in preparations for topical and vaginal use) *Tioconazole et ses sels (sauf dans les préparations pour usage topique et vaginal)*
4-5-04	Tiotropium bromide *Tiotropium (bromure de)*
1-3-01	Tirofiban and its salts and derivatives *Tirofiban et ses sels et dérivés*
29-9-99	Tizanidine and its salts *Tizanidine et ses sels*

	Tobramycin and its salts and derivatives
	Tobramycine, ses sels et dérivés
	Tocainide and its salts
	Tocaïnide et ses sels
	Tolazamide
	Tolazamide
	Tolazoline and its salts
	Tolazoline et ses sels
	Tolbutamide
	Tolbutamide
29-9-99	Tolcapone
	Tolcapone
4-5-04	Tolfenamic acid and its salts and derivatives
	Tolfénamique (acide), ses sels et dérivés
	Tolmetin and its salts
	Tolmétine et ses sels
29-9-99	Tolterodine and its salts
	Toltérodine et ses sels
14-5-98	Topiramate
	Topiramate
14-5-98	Topotecan and its salts
	Topotécane et ses sels
7-5-96	Torasemide and its salts
	Torasémide et ses sels
29-9-99	Toremifene and its salts
	Torémifène et ses sels
14-5-98	Trandolaprilat and its salts and derivatives
	Trandolaprilat et ses sels et dérivés
	Tranexamic acid
	Tranexamique (acide)
	Tranylcypromine
	Tranylcypromine
1-3-01	Trastuzumab
	Trastuzumab
	Trazodone and its salts
	Trazodone et ses sels
	Treosulfan
	Tréosulfan
22-6-06	Treprostinil and its salts
	Tréprostinil et ses sels
	Tretamine
	Trétamine
	Tretinoin (Vitamin A acid)
	Trétinoïne (acide de vitamine A)
7-5-96	Tretinoin and its salts and derivatives
	Trétinoïne, ses sels et dérivés
	Triamterene and its salts
	Triamtérène et ses sels
9-12-97	Tricaine and its salts
	Tricaïne et ses sels
	Trifluoperazine and its salts
	Trifluopérazine et ses sels
	Triflupromazine and its salts
	Triflupromazine et ses sels
	Trifluridine
	Trifluridine
	Trihexyphenidyl and its salts
	Trihexyphénidyle et ses sels
	Triiodothyropropionic acid
	Triiodothyropropionique (acide)
	Trilostane
	Trilostane
	Trimebutine and its salts
	Trimébutine et ses sels

	Trimethadione *Triméthadione*
	Trimethaphan camsylate *Trimétaphan (camsilate de)*
	Trimethoprim and its salts *Triméthoprime et ses sels*
	Trimetrexate and its salts *Trimétrexate et ses sels*
	Trimipramine and its salts *Trimipramine et ses sels*
	Trioxsalen *Trioxysalène*
14-5-98	Troglitazone *Troglitazone*
	Tropicamide and its salts in preparations for parenteral or ophthalmic use, except when sold for use in diagnostic procedures to an optometrist registered in a province of Canada *Tropicamide et ses sels dans les préparations pour usage ophtalmique ou parentéral, sauf lorsque vendu pour usage diagnostique à un optométriste enregistré dans une province du Canada*
18-5-00	Trovafloxacin and its salts and derivatives *Trovafloxacine et ses sels et dérivés*
	L-Tryptophan, when sold as a single ingredient *L-Tryptophane, s'il est vendu comme seul ingrédient*
14-5-98	Tubocurarine chloride *Tubocurarine (chlorure de)*
13-12-95	Tybamate *Tybamate*
	Tylosin and its salts and derivatives, when sold for the treatment of chronic colitis in dogs *Tylosine, ses sels et dérivés, lorsque vendu pour le traitement de la colite chronique chez le chien*
4-5-04	Unoprostone and its salts and derivatives *Unoprostone, ses sels et dérivés*
18-6-03	Uracil and its salts *Uracile et ses sels*
	Uracil mustard and its salts *Uracile (moutarde à l') et ses sels*
	Ursodeoxycholic acid and its salts *Ursodéoxycholique (acide) et ses sels*
4-5-04	Valdecoxib and its salts *Valdécoxib et ses sels*
4-5-04	Valganciclovir and its salts and derivatives *Valganciclovir, ses sels et dérivés*
	Valproic acid and its salts *Valproïque (acide) et ses sels*
14-5-98	Valaciclovir and its salts *Valaciclovir et ses sels*
21-11-02	Valrubicin and its derivatives *Valrubicine et ses dérivés*
29-9-99	Valsartan and its salts and derivatives *Valsartan et ses sels et dérivés*
	Vancomycin and its salts and derivatives *Vancomycine, ses sels et dérivés*
	Vasopressin and its salts *Vasopressine et ses sels*

	Vecuronium bromide *Vecuronium (bromure de)*
18-5-00	Vedaprofen and its salts and derivatives *Védaprofène et ses sels et dérivés*
7-5-96	Venlafaxine and its salts *Venlafaxine et ses sels*
	Verapamil and its salts *Vérapamil et ses sels*
2-10-03	Verteporfin and its salts and derivatives *Vertéporfine et ses sels et dérivés*
	Vidarabine *Vidarabine*
	Vigabatrin and its salts and derivatives *Vigabatrine, ses sels et dérivés*
	Vinblastine and its salts *Vinblastine et ses sels*
	Vincristine and its salts *Vincristine et ses sels*
	Vindesine and its salts *Vindésine et ses sels*
7-5-96	Vinorelbine and its salts *Vinorelbine et ses sels*
	Viomycin and its salts and derivatives *Viomycine, ses sels et dérivés*
4-12-97	Vitamin A in oral dosage form containing more than 10,000 International Units of Vitamin A per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by that person of more than 10,000 International Units of Vitamin A *Vitamine A présentée en unités posologiques orales contenant chacune plus de 10 000 unités internationales de vitamine A ou dont la plus forte dose quotidienne recommandée sur l'étiquette résulte en l'ingestion, par une personne, de plus de 10 000 unités internationales de vitamine A*
	Vitamin B12 with Intrinsic Factor Concentrate *Vitamine B12 avec concentré de facteur intrinsèque*
4-12-97	Vitamin D in oral dosage form containing more than 1,000 International Units of Vitamin D per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by the person of more than 1,000 International Units of Vitamin D *Vitamine D présentée en unités posologiques orales contenant chacune plus de 1 000 unités internationales de vitamine D ou dont la plus forte dose quotidienne recommandée sur l'étiquette résulte en l'ingestion, par une personne, de plus de 1000 unités internationales de vitamine D*
	Xanthinol nicotinate *Xantinol (nicotinate de)*
	Xylazine and its salts *Xylazine et ses sels*
13-12-95	
	Yohimbine and its salts *Yohimbine et ses sels*

	Zalcitabine and its salts *Zalcitabine et ses sels*
29-9-99	Zafirlukast and its salts *Zafirlukast et ses sels*
6-12-01	Zanamivir and its salts and derivatives *Zanamivir et ses sels et dérivés*
	Zidovudine *Zidovudine*
21-11-02	Zoledronic acid and its salts and derivatives *Acide zolédronique et ses sels et dérivés*
	Zomepirac and its salts *Zomépirac et ses sels*
	Zopiclone and its salts *Zopiclone et ses sels*
7-5-96	Zuclopenthixol and its salts and derivatives *Zuclopenthixol, ses sels et dérivés*

Acepromazine and its salts
Acépromazine et ses sels
Acetanilide
Acétanilide
Adrenocortical hormones and their salts and derivatives, except
(a) hydrocortisone or hydrocortisone acetate, when sold as a single medicinal ingredient in a concentration that provides 0.5% hydrocortisone in preparations for topical use on the skin; and
19-10-06 (b) clobetasone butyrate, when sold in a concentration of 0.05% clobetasone butyrate in cream preparations for topical use on the skin
Hormones corticosurrénales, leurs sels et dérivés sauf les suivants :
a) l'hydrocortisone et l'acétate d'hydrocortisone vendus en tant qu'ingrédient médicinal unique dont la concentration permet un apport en hydrocortisone de 0,5 % dans les préparations pour usage topique sur la peau;
b) le butyrate de clobétasone vendu sous forme de crème contenant 0,05 % de butyrate de clobétasone pour usage topique sur la peau
Aminopyrine and its derivatives
Aminopyrine et ses dérivés
Amprolium and its salts
Amprolium et ses sels
Antipyrine (except preparations for topical use)
Antipyrine (sauf dans les préparations pour usage topique)
Apramycin and its salts
Apramycine et ses sels
7-5-96 Azithromycin and its salts and derivatives
Azithromycine, ses sels et dérivés

Centella asiatica extract and active principles thereof
Centella asiatica (extrait de) et ses principes actifs
Chlorhexidine and its salts, when used as a topical oral preparation
Chlorhexidine et ses sels, dans les préparations pour usage oral topique
13-12-95 Chlorothiazide and its salts and derivatives
Chlorothiazide, ses sels et dérivés
Chlorpromazine and its salts
Chlorpromazine et ses sels
Cholestyramine resin
Colestyramine (résine de)
7-5-96 Clarithromycin and its salts and derivatives
Clarithromycine, ses sels et dérivés
Cyclizine
Cyclizine

Dihydrostreptomycin and its salts and derivatives
Dihydrostreptomycine, ses sels et dérivés
14-5-98 Dirithromycin
Dirithromycine

Ergot alkaloids and their salts
Ergot (alcaloïdes d') et leurs sels
13-12-95 Erythromycin and its salts and derivatives
Érythromycine, ses sels et dérivés

4-12-97 Folic acid
Acide folique
Framycetin and its salts and derivatives
Framycétine, ses sels et dérivés

Furaltadone and its salts
Furaltadone et ses sels
Furazolidone and its salts
Furazolidone et ses sels
Furosemide
Furosémide

Griseofulvin and its salts and derivatives
Griséofulvine, ses sels et dérivés

Iron derivatives for parenteral use only
Fer, ses dérivés pour usage parentéral seulement

4-5-04 Repealed by P.C. 2004-538 of May 4, 2004.

Kanamycin and its salts and derivatives
Kanamycine, ses sels et dérivés

Levamisole and its salts
Lévamisole et ses sels
Lincomycin and its salts and derivatives
Lincomycine, ses sels et dérivés
Liothyronine and its salts
Liothyronine et ses sels

13-12-95 Mebendazole
Mébendazole

23-3-00 Meclizine and its salts when sold in concentrations greater than 25 mg per dosage unit
Méclizine et ses sels s'ils sont vendus en une concentration supérieure à 25 mg par unité posologique

Neomycin and its salts and derivatives
Néomycine, ses sels et dérivés
Nicarbazin
Nicarbazin
Nitrofurantoin and its salts
Nitrofurantoine et ses sels
Novobiocin and its salts and derivatives
Novobiocine, ses sels et dérivés
Nystatin (except preparations for topical use on the skin) and its salts and derivatives
Nystatine (sauf dans les préparations pour usage topique sur la peau), ses sels et dérivés

Oleandomycin and its salts and derivatives
Oléandomycine, ses sels et dérivés

Penicillin and its salts and derivatives, (except amoxicillin, ampicillin, azlocillin, benzathine penicillin, carbenicillin, cloxacillin, dicloxacillin, hetacillin, mecillinam, methicillin, mezlocillin, nafcillin, oxacillin and ticarcillin and their salts and derivatives)
Pénicilline, ses sels et dérivés, (sauf amoxicilline, ampicilline, azlocilline, benzathine pénicilline, carbénicilline, cloxacilline, dicloxacilline, hétacilline, mécillinam, méthicilline, mezlocilline, nafcilline, oxacilline et ticarcilline, leurs sels et dérivés)
Physostigmine salicylate (except preparations for oral or topical use only)
Physostigmine (salicylate de), (sauf dans les préparations pour usage oral et topique seulement)
Polymyxin B and its salts and derivatives, (except for topical use or for local action in the oral cavity or nasal passages)
Polymyxine B, ses sels et dérivés, (sauf pour usage topique ou local dans la cavité buccale ou dans les voies nasales)
Primidone
Primidone
Promazine and its salts
Promazine et ses sels

Reserpine and its salts
Réserpine et ses sels
Ronidazole and its salts and derivatives
Ronidazole, ses sels et dérivés

Sex hormones, except the following:
Hormones sexuelles, sauf :

13-12-95
- Androisoxazole
  Androisoxazole
- Androstanolone
  Androstanolone
- Androstenediol and its derivatives
  Androstènediol et ses dérivés
- Bolandiol and its derivatives
  Bolandiol et ses dérivés
- Bolasterone
  Bolastérone
- Bolazine
  Bolazine
- Boldenone and its derivatives
  Boldénone et ses dérivés
- Bolenol
  Bolénol
- Calusterone
  Calustérone
- Clostebol and its derivatives
  Clostébol et ses dérivés
- Cyproterone and its derivatives
  Cyprotérone et ses dérivés
- Diethylstilbestrol and its derivatives
  Diéthylstilbestrol et ses dérivés
- Drostanolone and its derivatives
  Drostanolone et ses dérivés
- Enestebol
  Énestébol
- Epitiostanol
  Épitiostanol
- Ethylestrenol
  Éthylestrénol

Fluoxymesterone
Fluoxymestérone
Formebolone
Formébolone
Furazabol
Furazabol
4-Hydroxy-19-nortestosterone and its derivatives
Hydroxy-4-nor-19 testostérone et ses dérivés
19-4-05 Levonorgestrel, when sold in concentrations of 0.75 mg per oral dosage unit
Lévonorgestrel, s'il est vendu en une concentration de 0,75 mg par unité posologique orale

Mebolazine
Mébolazine
Megestrol and its derivatives
Mégestrol et ses dérivés
Mesabolone
Mésabolone
Mesterolone
Mestérolone
Metandienone
Métandiénone
Metenolone and its derivatives
Méténolone et ses dérivés
Methandriol
Méthandriol
Methyltestosterone and its derivatives
Méthyltestostérone et ses dérivés
Metribolone
Métribolone
13-12-95 Mibolerone
Mibolérone
Nandrolone and its derivatives
Nandrolone et ses dérivés
Norboletone
Norbolétone
Norclostebol and its derivatives
Norclostébol et ses dérivés
Norethandrolone
Noréthandrolone
Oxabolone and its derivatives
Oxabolone et ses dérivés
Oxandrolone
Oxandrolone
Oxymesterone
Oxymestérone
Oxymetholone
Oxymétholone
Prasterone
Prastérone
Quinbolone
Quinbolone
Stanozolol
Stanozolol
Stenbolone and its derivatives
Stenbolone et ses dérivés
Testosterone and its derivatives
Testostérone et ses dérivés
Tibolone
Tibolone

	Tiomesterone *Tiomestérone* Trenbolone and its derivatives *Trenbolone et ses dérivés* Zeranol *Zéranol*
	Sodium fluoride (in solid oral dosage forms containing more than one milligram of fluoride ion) *Sodium (fluorure de) (sous forme posologique solide orale contenant plus d'un milligramme d'ion fluor)* Spectinomycin and its salts and derivatives *Spectinomycine, ses sels et dérivés* Spiramycin and its salts and derivatives *Spiramycine, ses sels et dérivés* Streptomycin and its salts and derivatives *Streptomycine, ses sels et dérivés* Sulphonamides and their salts and derivatives *Sulfamides, leurs sels et dérivés*
	Tetracycline and its salts and derivatives (except doxycycline when sold for intramuscular administration in caged birds) *Tétracycline, ses sels et dérivés (sauf doxycycline si elle est vendue pour administration intramusculaire aux oiseaux en cage)*
13-12-95	Thiabendazole *Thiabendazole* Thyroid *Thyroïde* Tioconazole and its salts *Tioconazole et ses sels* Trimeprazine and its salts *Triméprazine et ses sels* Tylosin and its salts and derivatives (except when sold for the treatment of chronic colitis in dogs) *Tylosine, ses sels et dérivés (sauf lorsque vendu pour le traitement de la colite chronique chez le chien)*
	Veratrum album and its alkaloids and their salts *Veratrum album, ses alcaloïdes et leurs sels* Veratrum viride and its alkaloids and their salts *Veratrum viride, ses alcaloïdes et leurs sels* Virginiamycin and its salts and derivatives *Virginiamycine, ses sels et dérivés*
4-12-97	Vitamin A *Vitamine A*
4-12-97	Vitamin D *Vitamine D*
4-10-05	Vitamin K, except Vitamin K_1 and Vitamin K_2 sold (a) for external use in humans; or (b) in an oral dosage form for use in humans if the maximum recommended daily dose is 0.120 mg or less *Vitamine K, sauf la vitamine K_1 et la vitamine K_2 vendues :* *a) soit pour usage externe destiné aux humains;* *b) soit sous une forme posologique orale destinée aux humains si la dose quotidienne maximale recommandée est de 0,120 mg ou moins*

Short Title

1. These Regulations may be cited as the Cosmetic Regulations.

Interpretation

2. (1) In these Regulations,

"**Act**" means the *Food and Drugs Act; (Loi)*;

1-8-01 "**Assistant Deputy Minister**" means the Assistant Deputy Minister, Healthy Environments and Consumer Safety Branch, of the Department of Health; (*sous-ministre adjoint*)

16-11-04 * "**Assistant Deputy Minister**" Repealed by P.C. 2004-1326 of November 16, 2004.

16-11-04 * "**botanical**" means an ingredient that is directly derived from a plant and that has not been chemically modified before it is used in the preparation of a cosmetic; (*substance végétale*)

"**child-resistant container**" has the same meaning as in section 2 of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001; (*contenant protège-enfants*)

1-8-01 "**flame projection**" means the ability of the pressurized contents of an aerosol container to ignite and the length of that ignition, when tested in accordance with official method DO-30, *Determination of Flame Projection*, dated October 15, 1981; (*projection de flamme*)

"**flashback**" means that part of the flame projection that extends from its point of ignition back to the aerosol container when tested in accordance with official method DO-30, *Determination of Flame Projection*, dated October 15, 1981; (*retour de flamme*)

16-11-04 * "**ICI Dictionary**" means the *International Cosmetic Ingredient Dictionary and Handbook*, 10th edition (2004), published in Washington, D.C., U.S.A., by The Cosmetic, Toiletry, and Fragrance Association Inc., as amended from time to time; (*dictionnaire ICI*)

16-11-04 * "**INCI name**" means the International Nomenclature Cosmetic Ingredient name assigned to an ingredient in the ICI Dictionary; (*appellation INCI*)

16-11-04 * "**ingredient**" means any substance that is one of the components of a cosmetic and includes colouring agents, botanicals, fragrance and flavour, but does not include substances that are used in the preparation of the cosmetic but that are not present in the final product as a result of the chemical process; (*ingrédient*)

"**inner label**" means a label on or affixed to the immediate container of a cosmetic; (*étiquette intérieure*);

"**manufacturer**" means any person, partnership or unincorporated association that manufactures and, under its own name or under a trade mark, design, trade name or other name or mark owned or controlled by it, sells a cosmetic and includes any other person, partnership or unincorporated association that sells a cosmetic in such a manner; (*fabricant*)

16-11-04 * "**manufacturer**" means a person, a partnerhsip or an unincorporated association that sells, or manufactures and sells, a cosmetic under its own name or under a trade-mark, design, trade name or other name or mark owned or controlled by it; (*fabricant*)

23-7-81 "**official method**" means a method of analysis or examination designated as such by the Assistant Deputy Minister for use in the administration of the Act and these Regulations; (*méthode officielle*)

16-11-04 * "**official method**" means a method of analysis or examination designated as such by the Minister for use in the administration of the Act and these Regulations; (*méthode officielle*)

16-11-04 * "**ornamental container**" means a container that, except on the bottom, does not have any promotional or advertising material on it other than a trade-mark or common name, and that appears to be a decorative ornament because of a design that is on its surface or because of its shape or texture, and is sold as a decorative ornament in addition to being sold as the container of a cosmetic; (*contenant décoratif*)

* *Effective November 17, 2006 (two years after the day on which they are registered)*

"**outer label**" means a label on or affixed to the outside package of a cosmetic; (*étiquette extérieure*)

"**practitioner**" means a person who is registered and licensed under the laws of a province to practise the profession of medicine in that province; (*praticien*)

"**prescription**" means a direction given by a practitioner; (*ordonnance*)

12-12-91 "**principal display panel**" has the same meaning as in the Consumer Packaging and Labelling Regulations; (*espace principal*)

31-1-85 "**security package**" means a package having a security feature that provides reasonable assurance to consumers that the package has not been opened prior to purchase. (*emballage de sécurité*)

(2) Where a cosmetic has more than one name, a reference in these Regulations to the cosmetic by any of its names is deemed to be a reference to the cosmetic by all of its names.

Inspectors

3. (1) An inspector shall perform the functions and duties and carry out the responsibilities in respect of cosmetics prescribed by the Act and these Regulations.

(2) An inspector may, for the proper administration of the Act or these Regulations, take photographs of

(a) any cosmetic;
(b) any place where, on reasonable grounds, he believes any cosmetic is manufactured, prepared, preserved, packaged or stored;
(c) anything that, on reasonable grounds, he believes is used or capable of being used for the manufacture, preparation, preservation, packaging or storing of any cosmetic; and
(d) any labelling or advertising material relating to a cosmetic.

4-4-95 **4.** The certificate of designation required pursuant to subsection 22(2) of the Act shall

(a) certify that the person named therein is an inspector for the purpose of the Act; and
(b) be signed by the Assistant Deputy Minister and the person named in the certificate.

16-11-04 * **4.** Repealed by P.C. 2004-1326 of November 16, 2004.

Importation into Canada

5. Subject to section 9, no person shall import into Canada for sale a cosmetic the sale of which in Canada would constitute a violation of the Act or these Regulations.

6. An inspector may examine and take samples of any cosmetic sought to be imported into Canada.

7. Where an inspector examines or takes a sample of a cosmetic pursuant to section 6, he may submit the cosmetic or sample to an analyst for analysis or examination.

8. Where an inspector, on examination of a cosmetic or sample thereof or on receipt of a report of an analyst of the result of an analysis or examination of the cosmetic or sample, is of the opinion that the sale of the cosmetic in Canada would constitute a violation of the Act or these Regulations, the inspector shall so notify in writing the collector of customs concerned and the importer.

* *Effective November 17, 2006 (two years after the day on which they are registered)*

9. (1) Where a person seeks to import a cosmetic into Canada for sale and the sale would constitute a violation of the Act or these Regulations, that person may, if the sale of the cosmetic would be lawful in Canada after relabelling or modification of the cosmetic, import the cosmetic into Canada on condition that

(a) he gives to an inspector notice of the proposed importation; and
(b) the cosmetic will be relabelled or modified under the supervision of an inspector in such a manner as to enable the sale of the cosmetic to be lawful in Canada.

(2) No person shall sell a cosmetic that has been imported into Canada pursuant to subsection (1) unless the cosmetic has been relabelled or modified to the satisfaction of the inspector under whose supervision the relabelling or modification was carried out within three months after the importation of the cosmetic into Canada or within such longer period as the Assistant Deputy Minister may specify.

16-11-04 * (2) No person shall sell a cosmetic that has been imported into Canada under subsection (1) unless the cosmetic is relabelled or modified in accordance with the Act and these Regulations within three months after its importation.

10. No person shall import a cosmetic into Canada for sale unless the information and materials required by section 30 have been filed with the Assistant Deputy Minister in respect of that cosmetic.

16-11-04 ***10.** Repealed by P.C. 2004-1326 of November 16, 2004.

Sampling

11. Where an inspector takes a sample of a cosmetic pursuant to paragraph 22(1)(a) of the Act, he shall inform the owner thereof or the person from whom the sample is taken that he proposes to submit the sample or a part thereof to an analyst for analysis or examination and

16-11-04 ***11.** When an inspector takes a sample of a cosmetic under subsection 23(1) of the Act, the inspector shall inform the owner of the cosmetic or the person from whom the sample is taken that the inspector proposes to submit the sample or a part of it to an analyst for analysis or examination and

(a) where, in the opinion of the inspector, division of the procured quantity would not interfere with analysis or examination, he shall
  (i) divide the quantity into three parts,
  (ii) identify the three parts as the owner's portion, the sample and the duplicate sample and where only one part bears the label, identify that part as the sample,
  (iii) seal each part in such a manner that it cannot be opened without breaking the seal, and
  (iv) deliver the part identified as the owner's portion to the owner or the person from whom the sample was obtained and forward the sample and the duplicate sample to an analyst for analysis or examination; or

(b) where, in the opinion of the inspector, division of the procured quantity would interfere with analysis or examination, he shall
  (i) identify the entire quantity as the sample,
  (ii) seal the sample in such a manner that it cannot be opened without breaking the seal, and
  (iii) forward the sample to an analyst for analysis or examination.

Sales

12. No person shall sell a cosmetic if any label or advertisement of the cosmetic contains any symbol or statement that implies that the cosmetic has been compounded in accordance with a prescription.

13. No person shall sell a cosmetic recommended for removing stains from the teeth that has a measure of acidity greater than that represented by a pH of 4.

* *Effective November 17, 2006 (two years after the day on which they are registered)*

14. (1) No person shall sell a cosmetic for use in the area of the eye that contains any coal tar dye, coal tar dye base or coal tar dye intermediate.

28-4-89 (2) For the purpose of subsection (1) and section 15.1, "area of the eye" means the area bounded by the supraorbital and infraorbital ridges and includes the eyebrows, the skin underlying the eyebrows, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball and the soft tissue that lies below the eye and within the infraorbital ridge.

19-11-92 **15.** No manufacturer or importer shall sell a cosmetic that contains

(a) chloroform as an ingredient; or
(b) an estrogenic substance.

11-5-93 **15.1** No manufacturer or importer shall sell a cosmetic that contains mercury or a salt or derivative thereof unless

(a) the cosmetic is intended for use in the area of the eye;
(b) the mercury or its salt or derivative thereof is used in the cosmetic as a preservative; and
28-4-89 (c) the manufacturer or importer
(i) has in his possession evidence demonstrating that the only satisfactory way to maintain the sterility or stability of the cosmetic is to use mercury or a salt or derivative thereof as a preservative, and
(ii) at the request of the Assistant Deputy Minister, furnishes the Assistant Deputy Minister with the evidence referred to in subparagraph (i).

16-11-04 * (ii) at the Minister's request, provides the Minister with the evidence described in subparagraph (i).

16-8-94 **15.2** No person shall sell a cosmetic described in sections 28.2 to 28.4 unless it is packaged in a child-resistant container.

16-11-04 ***15.2** No person shall sell a cosmetic described in section 28.2 or 28.3 unless it is packaged in a child-resistant container.

16. No person shall sell a cosmetic unless it is labelled in accordance with these Regulations.

16-11-04 ***General**

Labelling

17. No reference, direct or indirect, to the Act or these Regulations shall be made on any label or in any advertisement of a cosmetic unless the reference is a specific requirement of the Act or these Regulations.

18. All information required by these Regulations to appear on the label of a cosmetic shall be

(a) clearly and prominently displayed thereon; and
(b) readily discernible to the purchaser or consumer under the customary conditions of purchase and use.

16-11-04 ***18.** The information required by these Regulations to be provided on the label of a cosmetic must

(a) be shown both in English and in French, except for the INCI name; and
(b) be clearly legible and remain so throughout the useful life of the cosmetic, or in the case of a refillable container, throughout its useful life, under normal conditions of sale and use.

19. Where a cosmetic has only one label, that label shall contain all the information required by these Regulations to be shown on both the inner and outer label thereof.

16-11-04 ***19.** If a cosmetic has only one label, that label must contain all the information required by these Regulations to be shown on both the inner and outer labels.

* *Effective November 17, 2006 (two years after the day on which they are registered)*

20. Subject to these Regulations, the inner label of a cosmetic shall show

(a) the name of the manufacturer or distributor of the cosmetic and the address of his principal place of business; and

16-11-04 * (a) the name of the manufacturer and the address of their principal place of business; and

(b) the identity of the cosmetic in terms of its common or generic name or in terms of its function, unless the identity is obvious.

21. (1) No manufacturer shall, on any label or in any advertisement for a cosmetic, make any claim respecting

(a) the ability of the product or any ingredient thereof to influence the chemistry of the skin, hair or teeth, or

(b) product formulation, manufacture or performance that would imply that the user of the product will not suffer injury to health

unless the manufacturer is in possession of evidence validating the claim.

(2) The manufacturer shall, on request, furnish the Assistant Deputy Minister with the evidence referred to in subsection (1).

16-11-04 ***21.** (1) No manufacturer shall make any claim on a label of or in an advertisement for a cosmetic respecting either of the following, unless the manufacturer has evidence that validates the claim:

(a) the ability of the cosmetic or any of its ingredients to influence the chemistry of the skin, hair or teeth; or

(b) the formulation, manufacture or performance of the cosmetic that would imply that the user of the cosmetic will not suffer injury to their health.

(2) The manufacturer shall, on request, provide the Minister with the evidence referred to in subsection (1).

List of Ingredients

***21.1** Sections 21.2 to 21.5 do not apply to any product whose ingredient labelling is regulated under the *Food and Drug Regulations* or the *Natural Health Products Regulations*.

***21.2** (1) Subject to subsection (4), a list of ingredients must appear on the outer label of a cosmetic, with each ingredient listed only by its INCI name.

16-11-04 (2) In the case of makeup and nail polish and enamel sold in a range of colour shades, all colouring agents used in the range may be listed if they are preceded by the symbol "+/-" or "±" or the phrase "may contain/peut contenir".

(3) Botanicals must be listed by specifying at least the genus and species portions of the INCI name.

(4) An ingredient that is included in the schedule may be listed either by its EU trivial name set out in column 1 of the schedule or by the appropriate English and French equivalents set out in columns 2 and 3.

***21.3** An ingredient that has no INCI name must be listed by its chemical name.

***21.4** (1) Subject to subsections (2) and (3), ingredients must be listed in descending order of predominance, in their concentration by weight.

(2) Ingredients that are present at a concentration of 1% or less and all colouring agents, regardless of their concentration, may be listed in random order after the ingredients that are present at a concentration of more than 1%.

(3) In the case of fragrance and flavour, the words "parfum" and "aroma", respectively, may be inserted at the end of the list of ingredients to indicate that such ingredients have been added to the cosmetic to produce or to mask a particular odour or flavour.

* *Effective November 17, 2006 (two years after the day on which they are registered)*

***21.5** (1) Despite subsection 21.2(1), in the case of a cosmetic whose immediate container or outside package is so small that the label cannot comply with the requirements of paragraph 18(b), the list of ingredients may appear on a tag, tape or card affixed to the container or package.

16-11-04 (2) Despite subsection 21.2(1), in the case of a cosmetic in an ornamental container that has no outside package, the list of ingredients may appear on a tag, tape or card affixed to the container.

(3) Despite subsection 21.2(1), in the case of a cosmetic that has no outside package and whose size, shape or texture, or that of its immediate container, makes it impractical for a tag, tape or card to be affixed to the container, the list of ingredients may instead appear in a leaflet that must accompany the cosmetic at the point of sale.

22. (1) Subject to subsection (2), no person shall sell a hair dye that contains paraphenylenediamine or other coal tar dye base or coal tar dye intermediate unless

(a) both the inner and the outer labels thereof carry the following warning:
"CAUTION: This product contains ingredients that may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows. To do so may cause blindness."
"MISE EN GARDE: Ce produit contient des ingrédients qui peuvent causer de l'irritation cutanée chez certaines personnes: il faut donc d'abord effectuer une épreuve préliminaire selon les directives ci-jointes. Ce produit ne doit pas servir à teindre les sourcils ni les cils: en ce faisant, on pourrait provoquer la cécité", and

(b) instructions to the following effect in both official languages, accompany each package of the hair dye:
(i) the preparation may cause serious inflammation of the skin in some persons and a preliminary test should always be carried out to determine whether or not special sensitivity exists, and
(ii) to make the test, a small area of skin behind the ear or on the inner surface of the forearm should be cleansed, using either soap and water or alcohol, and a small quantity of the hair dye as prepared for use should be applied to the area and allowed to dry. After 24 hours, the area should be washed gently with soap and water. If no irritation or inflammation is apparent, it is usually assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each application. On no account should the hair dye be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result.

28-4-89 **22.1** The outer label of a cosmetic, where that cosmetic contains mercury or a salt or derivative thereof as a preservative, shall indicate the name of the preservative and its concentration in the cosmetic.

Particular Requirements for Certain Cosmetics

***22.** A hair dye that contains paraphenylenediamine or other coal tar dye base or coal tar intermediate must

(a) carry the following warning on both the inner and outer labels:
"CAUTION: This product contains ingredients that may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows. To do so may cause blindness.
MISE EN GARDE : Ce produit contient des ingrédients qui peuvent causer de l'irritation cutanée chez certaines personnes; il faut donc d'abord effectuer une épreuve préliminaire selon les directives ci-jointes. Ce produit ne doit pas servir à teindre les sourcils ni les cils; en ce faisant, on pourrait provoquer la cécité."; and

16-11-04 (b) be accompanied by instructions to the following effect:
(i) the preparation may cause serious inflammation of the skin in some persons, and a preliminary test should always be made to determine whether special sensitivity exists, and
(ii) to make the test, a small area of skin behind the ear or on the inner surface of the forearm should be cleansed, using either soap and water or alcohol, and a small quantity of the hair dye as prepared for use should be applied to the area and allowed to dry. After 24 hours, the area should be washed gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should be made before each application. The hair dye should never be used for dyeing eyebrows or eyelashes, as severe inflammation of the eye or even blindness may result.

* *Effective November 17, 2006 (two years after the day on which they are registered)*

23. A deodorant that is intended for use in the genital area and that is sold in a pressurized container shall carry the following information on both its inner and outer labels:

"Directions: For external use only. Use sparingly and not more than once daily. Spray external skin surface while holding nozzle at least 8 inches from the skin."
"Mode d'emploi: Pour usage externe seulement. Employer modérément, pas plus d'une fois par jour Vaporiser sur la surface externe de la peau en tenant le bec à une distance d'au moins 8 pouces."

"Caution: Do not apply internally or to broken, irritated or itching skin. Do not use when wearing a sanitary napkin. Discontinue use immediately if a rash or irritation develops. Consult a physician if the rash or irritation persists or if there is any unusual odour or discharge at any time."
"Mise en garde: Ne pas appliquer sur une surface interne ou sur une surface éraflée, irritée ou en proie à la démangeaison. Ne pas utiliser avec des serviettes hygiéniques. Cesser immédiatement l'emploi en cas d'éruption ou d'irritation. Consulter un médecin si l'éruption ou l'irritation persiste ou en cas d'odeur ou de sécrétion inhabituelle."

28-4-89 **24.** (1) No person shall sell a cosmetic presenting an avoidable hazard unless the label carries, in both official languages adequate directions for safe use.

(2) For the purpose of subsection (1), "avoidable hazard" means a threat of injury to the health of the user of a cosmetic that can be

(a) predicted from the composition of the cosmetic, the toxicology of the ingredients and the site of application thereof;
(b) reasonably anticipated during normal use; and
(c) eliminated by specified limitations on the usage of the cosmetic.

***24.** (1) The label of a cosmetic that presents an avoidable hazard must include adequate directions for safe use.

16-11-04

(2) For the purpose of subsection (1), "avoidable hazard" means a threat of injury to the health of the user of a cosmetic that can be

(a) predicted from the cosmetic's composition, the toxicology of its ingredients and the site of its application;
(b) reasonably anticipated during normal use; and
(c) eliminated by specified limitations on the usage of the cosmetic.

16-11-04 ***Pressurized Containers**

1-8-01 **25.** (1) Subject to subsection (3) and section 27, in the case of a cosmetic packaged in a disposable metal container designed to release pressurized contents by use of a manually operated valve that forms an integral part of the container, the principal display panel of the inner and outer labels of the cosmetic shall display, in accordance with sections 15 to 18 of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following information:

12-12-91 (a) the hazard symbol set out in column II of item 10 of Schedule II to those Regulations, accompanied by the signal word "**CAUTION / ATTENTION**"; and
(b) the primary hazard statement "**CONTAINER MAY EXPLODE IF HEATED. / CE CONTENANT PEUT EXPLOSER S'IL EST CHAUFFÉ.**"

1-8-01 (2) Subject to subsection (3) and section 27, one panel of the inner and outer labels of a cosmetic referred to in subsection (1) shall display, in the size required by paragraph 19(1)(b) of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following additional hazard statement:

12-12-91 "Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store at temperatures over 50°C.
Contenu sous pression. Ne pas mettre dans l'eau chaude ni près des radiateurs, poêles ou autres sources de chaleur. Ne pas percer le contenant, ni le jeter au feu, ni le conserver à des températures dépassant 50°C."

* *Effective November 17, 2006 (two years after the day on which they are registered)*

(3) Where the Assistant Deputy Minister has determined, at the request of the manufacturer, that the materials used in the construction of a container described in subsection (1) or the incorporation in that container of a safety device has eliminated the hazards presented by the container, subsections (1) and (2) do not apply to the cosmetic packaged in that container."

16-11-04 * (3) If the Minister determines, at the request of the manufacturer, that the materials used in the construction of a container described in subsection (1) or the incorporation in such a container of a safety device has eliminated the hazards presented by the container, subsections (1) and (2) do not apply to the cosmetic packaged in that container.

(4) Revoked by P.C. 1981-2048 of July 23, 1981.

23-7-81

(5) Revoked by P.C. 1981-2048 of July 23, 1981.

1-8-01 **26.** (1) Subject to section 27, if a cosmetic is packaged in a container described in subsection 25(1) and has a flame projection of a length set out in column I of any of items 1 to 3 of the table to this subsection or has a flashback as set out in column I of item 4 of that table, as determined by official method DO-30, *Determination of Flame Projection*, dated October 15, 1981, the principal display panel of the inner label of and outer label for the cosmetic shall display, in accordance with sections 15 to 18 of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following information:

12-12-91

(a) the hazard symbol set out in column II of the same item;
(b) in both official languages, the signal word set out in column III of the same item; and
(c) in both official languages, the primary hazard statement set out in column IV of the same item.

16-11-04 * (a) the hazard symbol set out in column II;
(b) the signal word set out in column III; and
(c) the primary hazard statement set out in column IV.

* *Effective November 17, 2006 (two years after the day on which they are registered)*

TABLE

12-12-91

Item	Column I Flame Projection Length --- Flashback	Column II Hazard Symbol	Column III Signal Word	Column IV Primary Hazard Statement
1.	Less than 15 cm		Caution	Flammable
2.	15 cm or more but less than 45 cm		Warning	Flammable
3.	45 cm or more		Danger	Extremely Flammable
4.	Flashback		Danger	Extremely Flammable

23-7-81

12-12-91

1-8-01

(2) In addition to the requirements of subsection (1), one panel of the inner label and outer labels of a cosmetic referred to in that subsection shall display, in the size required by paragraph 19(1)(b) of the Consumer Chemicals and *Containers Regulations* as they read on September 30, 2001, the following additional hazard statements:
"Do not use in presence of open flame or spark.
Ne pas utiliser en présence d'une flamme nue ou d'étincelles."

27. (1) Where the labelled net quantity of a container of a cosmetic described in subsection 25(1) or 26(1) does not exceed 60 millilitres or 60 grams, the inner label may show only the information described in paragraph 25(1)(a) or paragraphs 26(1)(a) and (b), as the case may be.

23-7-81

(2) Where the labelled net quantity of a container of a cosmetic described in subsection 25(1) or 26(1) exceeds 60 millilitres or 60 grams but does not exceed 120 millilitres or 120 grams the inner label may show only the information described in subsection 25(1) or subsection 26(1), as the case may be.

12-12-91

(3) Where the labelled net quantity, in a container, of a cosmetic described in subsection 25(1) or 26(1) is less than 30 mL or 30 g, the hazard symbol shall be of such size as to be capable of being circumscribed by a circle with a diameter of at least 6 mm.

23-7-81

(4) Where a container of a cosmetic described in subsection (1) or (2) is sold in a package, the outer label may show only the information described in subsection 25(2) and where applicable, subsection 26(2).

16-11-04

***27.** (1) When the labelled net quantity of a cosmetic described in subsection 25(1) or 26(1) is less than 30 mL or 30 g, the hazard symbol must be of such a size that it is capable of being circumscribed by a circle with a diameter of at least 6 mm.

(2) When the labelled net quantity of a cosmetic described in subsection 25(1) or 26(1) is not greater than 60 mL or 60 g, the inner label may show only the information described in paragraph 25(1)(a) or paragraphs 26(1)(a) and (b), as the case may be.

(3) When the labelled net quantity of a cosmetic described in subsection 25(1) or 26(1) is greater than 60 mL or 60 g but not greater than 120 mL or 120 g, the inner label may show only the information described in subsection 25(1) or 26(1), as the case may be.

(4) When a cosmetic described in subsection (2) or (3) is sold in an outside package, the outer label may show only the information described in subsection 25(2) and, if applicable, subsection 26(2).

* *Effective November 17, 2006 (two years after the day on which they are registered)*

11-5-93 **28.** Revoked by P.C. 1993-940 of May 11, 1993.

28.1 (1) Subject to subsection (2) no person shall sell a mouthwash for human use unless it is contained in a security package.

(2) Subsection (1) applies only to mouthwash that is available to the public in an open self-selection area or that is distributed as a sample.

28-4-89

(3) Unless the security feature of a security package referred to in subsection (1) is self-evident and is an integral part of the immediate product container, the inner label of the security package shall carry a statement or illustration drawing attention to the security feature of the package and, if the security feature is part of an outer package, the outer label shall also carry the statement or illustration.

16-11-04 * (3) Unless the security feature of a security package is self-evident and is an integral part of the immediate container, the inner label of the security package must carry a statement or illustration that draws attention to the security feature of the package and, if the security feature is part of an outside package, the outer label must also carry the statement or illustration.

16-8-94 **28.2** The principal display panel of the inner label and the outer label of the container of a cosmetic, other than a disposable metal container designed to release pressurized contents by the use of a manually operated valve that forms an integral part of the container, that contains an amount of methyl alcohol equal to or greater than 5 mL, shall display

16-11-04 ***28.2** The principal display panel of the inner and outer labels of a cosmetic, other than one in a container described in subsection 25(1), that contains 5 mL or more of methyl alcohol must display all of the following information:

(a) the hazard symbol set out in column II of item 1 of Schedule II to the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, in accordance with paragraphs 16(a) and (b) of those Regulations; and

1-8-01 (b) for each of the particulars set out in column I of items 1 to 5 of the table to section 46 of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the signal word and statements set out in columns III and IV of those items, which shall be located on the labels in accordance with paragraphs 15(2)(a) and (c) of those Regulations and printed in accordance with paragraphs 17(a) and (b), 18(a) and (b) and 19(1)(a) and (b) and subsection 19(2) of those Regulations.

16-11-04 * (b) for each of the particulars set out in column I of items 1 to 5 of the table to section 46 of the *Consumer Chemicals and Containers Regulations* , as they read on September 30, 2001, the signal word and statements set out in columns III and IV of those items, which must be located on the labels in accordance with paragraphs 15(2)(a) to (c) of those Regulations and printed in accordance with paragraphs 17(a) and (b), 18(a) and (b) and 19(1)(a) and (b) and subsection 19(2) of those Regulations.

28.3 The inner label and the outer label of a cosmetic, in liquid form, that contains an amount of sodium bromate ($NaBrO_3$) equal to or greater than 600 mg or an amount of potassium bromate ($KBrO_3$) equal to or greater than 50 mg, shall carry a statement to the effect that the product contains sodium bromate or potassium bromate, as the case may be, is poisonous, is to be kept out of reach of children and, in the case of accidental ingestion, a Poison Control Centre or physician is to be contacted immediately.

16-8-94

28.4 The inner label and the outer label of a cosmetic, in liquid form, that contains an amount of acetonitrile equal to or greater than 500 mg shall carry a statement to the effect that the product contains acetonitrile, is poisonous, is to be kept out of reach of children and, in the case of accidental ingestion, a Poison Control Centre or physician is to be contacted immediately.

16-11-04 ***28.3** The inner and outer labels of a cosmetic in liquid form that contains 600 mg or more of sodium bromate ($NaBrO_3$) or 50 mg or more of potassium bromate ($KBrO_3$) must carry a statement to the effect that the product contains sodium bromate or potassium bromate, as the case may be, is poisonous, is to be kept out of the reach of children and, in the case of accidental ingestion, a Poison Control Centre or physician is to be contacted immediately. *(Replaces sections 28.3 and 28.4)*

* *Effective November 17, 2006 (two years after the day on which they are registered)*

Evidence of Safety of Cosmetics

29. (1) The Assistant Deputy Minister may, in writing, request the manufacturer of a cosmetic to submit to him, on or before a specified day, evidence to establish the safety of the cosmetic under the recommended conditions of use of the cosmetic or when used under such methods of use as are customary or usual therefor.

(2) Where the manufacturer of a cosmetic is requested by the Assistant Deputy Minister pursuant to subsection (1) to submit evidence of the safety with respect to a cosmetic, the manufacturer shall cease to sell that cosmetic after the day specified in the request unless he has duly submitted the evidence requested.

(3) Where the Assistant Deputy Minister is of the opinion that the evidence submitted by a manufacturer pursuant to subsection (1) is not sufficient, he shall notify the manufacturer in writing to that effect and the manufacturer shall not thereafter sell the cosmetic unless

(a) he has submitted further evidence to the Assistant Deputy Minister; and
(b) he has been notified in writing by the Assistant Deputy Minister that the further evidence is sufficient.

***29.** (1) The Minister may request in writing that a manufacturer submit to the Minister, on or before a specified day, evidence to establish the safety of a cosmetic under the recommended or the normal conditions of use.

(2) A manufacturer who does not submit the evidence requested under subsection (1) shall cease to sell the cosmetic after the day specified in the request.

16-11-04

(3) If the Minister is of the opinion that the evidence submitted by a manufacturer under subsection (1) is not sufficient, the Minister shall notify the manufacturer in writing to that effect, and the manufacturer shall cease to sell the cosmetic until the manufacturer

(a) has submitted further evidence to the Minister; and
(b) has been notified in writing by the Minister that the further evidence is sufficient.

Notification

30. (1) Every manufacturer of a cosmetic shall within 10 days from the day on which he first sells the cosmetic, furnish the Assistant Deputy Minister with

(a) a notification on a form obtained from the Assistant Deputy Minister and signed by the manufacturer or a person authorized on his behalf, advising whether he intends to continue sales of the cosmetic in Canada and including the information described in subsection (2); and
(b) a copy or facsimile of the labels and inserts used in conjunction with the cosmetic where the labels and inserts require the information set out in sections 22 to 24.

(2) For the purpose of paragraph (1)(a), the information described in this subsection is

(a) the name and address of every person, firm, partnership or corporation appearing on the label of the cosmetic sold by the manufacturer;
(b) the name under which the cosmetic is sold;
(c) the purpose of the cosmetic;
(d) a list of ingredients contained in the cosmetic and, for each ingredient, the exact concentration or the concentration range that includes the concentration of that ingredient which may be shown by the numbers indicated as applying to the concentration range on the table to this section;
(e) the form of the cosmetic;
(f) the name and address of the Canadian distributor;
(g) where the cosmetic was not manufactured or formulated by the person whose name appears on the label of the cosmetic, the name and address of the person who manufactured or formulated the cosmetic; and
(h) the name and office of the person who signed the notification referred to in paragraph (1)(a).

* *Effective November 17, 2006 (two years after the day on which they are registered)*

*30. (1) Every manufacturer and importer shall provide the Minister with the following documents, at the latest 10 days after the manufacturer or importer first sells a cosmetic:

(a) a notification or a form obtained from the Minister and signed by the manufacturer or importer, as the case may be, or a person authorized on their behalf, advising whether they intend to continue sales of the cosmetic in Canada and including the information specified in subsection (2); and
(b) if the labels and inserts used in conjunction with the cosmetic require the information set out in any of sections 22 to 24, a copy or facsimile of the labels and inserts.

(2) The following is the information required for the purpose of paragraph (1)(a):

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(a) the name and address of the manufacturer that appears on the label of the cosmetic in accordance with section 20;
(b) the name under which the cosmetic is sold;
(c) the function of the cosmetic;
(d) a list of the cosmetic's ingredients and, for each ingredient, its exact concentration or the concentration range that includes its concentration, as set out in the table to this section;
(e) the form of the cosmetic;
(f) the name and address in Canada of the manufacturer, importer or distributor;
(g) if the cosmetic was not manufactured or formulated by the person whose name appears on the label, the name and address of the person who manufactured or formulated it; and
(h) the name and title of the person who signed the notification referred to in paragraph (1)(a).

TABLE

Number		Range		
1	over	30%	to	100%
2	over	10%	to	30%
3	over	3%	to	10%
4	over	1%	to	3%
5	over	0.3%	to	1%
6	over	0.1%	to	0.3%
7		0.1%	or less	

31. The manufacturer of a cosmetic who has furnished the Assistant Deputy Minister with a notification pursuant to section 30 shall, where any information or material furnished therewith becomes no longer accurate, furnish the Assistant Deputy Minister, within 10 days, with a revised notification together with such revised materials as may be applicable.

32. Any manufacturer who has furnished the Assistant Deputy Minister with a notification pursuant to section 30 shall promptly furnish the Assistant Deputy Minister with such additional information respecting the cosmetic as the Assistant Deputy Minister may from time to time request.

*31. A manufacturer or importer who has provided the Minister with a notification under section 30 shall

16-11-04

(a) provide the Minister with a revised notification, together with any applicable revised document or information, within 10 days after the document or information becomes inaccurate; and
(b) promptly provide the Minister with any additional information respecting the notification that the Minister may request. *(Replaces sections 31. and 32.)*

* *Effective November 17, 2006 (two years after the day on which they are registered)*

Schedule
(*Section 23*)

SCHEDULE
(*Subsection 21.2(4)*)

EU TRIVIAL NAMES AND THEIR ENGLISH
AND FRENCH EQUIVALENTS

	Column 1	Column 2	Column 3
Item	*EU Trivial Name*	*English Equivalent*	*French Equivalent*
1.	Acetum	Vinegar	Vinaigre
2.	Adeps Bovis	Tallow	Suif
3.	Adeps Suillus	Lard	Saindoux
4.	Aqua	Water	Eau
5.	Bassia Latifolia	Illipe Butter	Beurre d'illipe
6.	Beta Vulgaris	Beet Root Extract	Extrait de racine de betterave
7.	Bombyx	Silk Worm Extract	Extrait de ver à soie
8.	Brevoortia	Menhaden Oil	Huile de menhaden
9.	Bubulum	Neatsfoot Oil	Huile de pied de boeuf
10.	Butyris Lac	Buttermilk Powder	Babeurre en poudre
11.	Butyrum	Butter	Beurre
16-11-04 12.	Candelilla Cera	Euphorbia Cerifera (Candelilla) Wax	Cire de candelilla
13.	Canola	Canola Oil Canola Oil Unsaponifiables	Huile de colza Huile de colza enrichie en insaponifiables
14.	Caprae Lac	Goat Milk	Lait de chèvre
15.	Cera Alba	Beeswax	Cire d'abeille
16.	Cera Carnauba	Copernicia Cerifera (Carnauba) Wax	Cire de carnauba
17.	Cera Microcristallina	Microcrystalline Wax	Cire microcristalline
18.	Colophonium	Rosin	Colophane
19.	Dromicelus	Emu Oil	Huile d'émeu
20.	Faex	Lactic Yeast Yeast Yeast Extract	Levure lactique Levure Extrait de levure
21.	Gadi Lecur	Cod Liver Oil	Huile de foie de morue
22.	Hoplostethus	Orange Roughy Oil	Huile d'hoplostète orange
23.	Hordeum Distichon	Barley Extract Barley Seed Flour	Extrait d'orge à deux rangs Farine d'orge à deux rangs

* *Effective November 17, 2006 (two years after the day on which they are registered)*

Item	Column I *EU Trivial Name*	Column 2 *English Equivalent*	Column 3 *French Equivalent*
24.	Hordeum Vulgare	Hordeum Vulgare Extract Hordeum Vulgare Juice Hordeum Vulgare Leaf Juice Hordeum Vulgare Powder Hordeum Vulgare Root Extract Hordeum Vulgare Seed Extract Hordeum Vulgare Seed Flour Spent Grain Flour	Extrait d'orge Jus d'orge Jus des feuilles d'orge Poudre d'orge Extrait de racine d'orge Extrait de semence d'orge Farine d'orge Farine de drêche
25.	Lac	Milk Whole Dry Milk	Lait Lait entier en poudre
26.	Lactis Lipida	Milk Lipids	Lipides du lait
27.	Lactis Proteinum	Milk Protein Whey Protein	Protéine du lait Protéine du petit-lait
28.	Lanolin Cera	Lanolin Wax	Cire de lanoline
29.	Maris Aqua	Sea Water	Eau de mer
30.	Maris Limus	Sea Silt Extract	Extrait de limon marin
31.	Maris Sal	Sea Salt	Sel marin
16-11-04 32.	Mel	Honey Honey Extract	Miel Extrait de miel
33.	Montan Cera	Montan Wax	Cire de Montan
34.	Mortierella Isabellina	Mortierella Oil	Huile de Mortierella
35.	Mustela	Milk Oil Mink Wax	Huile de vison Cire de vison
36.	Olus	Vegetable Oil	Huile végétale
37.	Ostrea	Oyster Shell Extract	Extrait de coquille d'huître
38.	Ovum	Dried Egg Yolk Egg Egg Oil Egg Powder Egg Yolk Extract	Poudre de jaune d'œufs Œuf Huile d'œuf Poudre d'œufs Extrait de jaune d'œuf
39.	Paraffinum Liquidum	Mineral Oil	Huile minérale
40.	Pellis Lipida	Skin Lipids	Lipides cutanés
41.	Pisces	Fish Extract	Extrait de poisson
42.	Piscum Lecur	Fish Liver Oil	Huile de foie de poisson
43.	Pix	Tar Oil	Huile d'anthracène
44.	Propolis Cera	Propolis Wax	Cire de propolis

* *Effective November 17, 2006 (two years after the day on which they are registered)*

Item	Column 1 *EU Trivial Name*	Column 2 *English Equivalent*	Column 3 *French Equivalent*
45.	Saccharum Officinarum	Black Strap Powder Molasses Extract Sugar Cane Extract	Poudre de mélasse Extrait de mélasse Extrait de canne à sucre
46.	Salmo	Salmon Egg Extract Salmon Oil	Extrait d'œufs de saumon Huile de saumon
47.	Sepia	Cuttlefish Extract	Extrait de seiche
48.	Serica	Silk Silk Powder	Soie Poudre de soie
49.	Shellac Cera	Shellac Wax	Cire de laque
16-11-04 50.	Sine Adipe Colostrum	Nonfat Dry Colostrum	Poudre de colostrum écrémé
51.	Sine Adipe Lac	Nonfat Dry Milk	Poudre de lait écrémé
52.	Solum Diatomeae	Diatomaceous Earth	Terre de diatomées
53.	Solum Fullonum	Fuller's Earth	Terre à foulon
54.	Squali Lecur	Shark Liver Oil	Huile de foie de requin
55.	Sus	Pigskin Extract	Extrait de peau de porc
56.	Tallol	Tall Oil	Tallöl
57.	Vitulus	Brain Extract Brain Lipids Calf Blood Extract Calf Skin Extract Hydrolyzed Calf Skin Liver Extract	Extrait de cerveau Lipides du cerveau Extrait de sang de veau Extrait de peau de veau Peau de veau hydrolysée Extrait de foie

* *Effective November 17, 2006 (two years after the day on which they are registered)*

Interpretation

1. The definitions in this section apply in these Regulations.

"assisted conception" means a reproductive technique performed on a woman for the purpose of conception, using semen from a donor who is not her spouse or sexual partner. (*reproduction assistée*)

"container" means a straw, vial, ampoule or similar receptacle used to contain semen, that is in direct contact with the semen. (*récipient*)

27-7-00 | "Directive" means the directive entitled *Technical Requirements for Therapeutic Donor Insemination*, published by the Department of Health, Ottawa, July 2000. (*directive*)

1-12-00 | "Director" Repealed by P.C. 2000-1708 of November 30, 2000.

27-7-00 | "Guidelines" Repealed by P.C. 2000-1100 of July 27, 2000.

1-12-00 | "health care facility" means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has common responsibility for the activities carried out in those facilities. (*établissement de santé*)

27-7-00 | "process", in respect of semen, means to collect, test, prepare, preserve, label and store the semen for use in assisted conception, and includes the measures referred to in paragraph 9(1)(a). (*traitement*)

Application

2. These Regulations apply only in respect of semen that is used or intended for use in assisted conception.

Food and Drug Regulations

3. (1) The provisions of Part A of the *Food and Drug Regulations* in respect of the importing, labelling and packaging of drugs do not apply in respect of semen.

(2) Part C of the *Food and Drug Regulations* does not apply in respect of semen.

1-12-00 | **PART 1**
GENERAL

Prohibition

4. (1) No person shall distribute semen unless

(a) the semen has been processed in accordance with sections 9 to 11; and

(b) after the semen has been quarantined for a minimum of six months,

(i) it is determined that the donor is still not within a group set out in the Directive under the heading "Exclusions", and

27-7-00 | (ii) the donor is re-tested as set out in the Directive under the heading "Repeat Screening & Quarantine", using the tests specified therein or other tests that are at least as effective as those tests in detecting the infectious agents specified therein, and the results of the tests are negative.

27-7-00 | (1.1) Any test referred to in subparagraph (1)(b)(ii) must meet the requirements set out in clause 3.5.1.1 of the Directive.

*(R) Minor correction

1-12-00

(2) No person shall distribute semen that is required to be quarantined or destroyed under paragraph 9(1)(b), 15(1)(a), 16(2)(c) or (d) or subsection 17(1) or (3).

(3) Subject to section 5.1, no person shall distribute semen that is required under paragraph 16(3)(c) or (d) or 17(4)(a) to be quarantined, destroyed or reserved for special access distribution.

5. No person shall import semen for distribution unless

(*a*) it meets the requirements set out in subsection 4(1); and

(*b*) the outer shipping container in which the semen is transported displays clearly, on the outside surface of that container,

(i) the name and business address of the processor, and

(ii) a declaration, signed by the processor or an authorized agent of the processor, certifying that the semen has been processed in accordance with these Regulations and quarantined for a minimum of six months.

Exception

1-12-00

5.1 Despite subsection 4(1) and section 5, a person may distribute or import for distribution semen that has not been processed in accordance with the requirements of paragraphs 4(1)(b) and 9(1)(a) and section 10 or that has been reserved for special access distribution if the person does so in accordance with a special access authorization issued under section 20.

Notice

1-12-00

6. (1) Every person who processes or imports, or intends to process or import, semen for distribution shall give written notice to the Minister of the processing or importing at least 10 days before the date on which they begin processing or importing semen.

(*a*) on or before August 1, 1996, if they began processing or importing semen before June 1, 1996; or

(*b*) at least 10 days before the date on which they begin processing or importing semen, if that date is on or after June 1, 1996.

(2) The notice shall be signed and dated by the processor or importer, or an authorized agent of the processor or importer, and shall include

(*a*) the name and business address of the processor or importer;

(*b*) if the notice is signed by an authorized agent, the name and title of the agent; and

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(*c*) the date of beginning to process or import semen.

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7. A processor or importer of semen shall provide any additional information that the Minister may in writing request, on or before the date set out in the request, in order to establish that the semen has been processed in accordance with these Regulations.

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8. (1) Every person shall, within 90 days after they have stopped processing or importing semen, give written notice to the Minister indicating that they have stopped processing or importing semen.

(2) The notice shall be signed and dated by the processor or importer, or an authorized agent of the processor or importer, and shall include

(*a*) the name and business address of the processor or importer;

(*b*) if the notice is signed by an authorized agent, the name and title of the agent; and

(*c*) the date on which the processor or importer stopped processing or importing semen.

Screening

9. (1) Every person who processes semen for distribution shall

(*a*) take the following measures:

(i) determine that the donor is not within a group set out in the Directive under the heading "Exclusions",

27-7-00 (ii) perform the tests specified in the Directive under the headings "Work-up", "Repeat Screening & Quarantine" and "Microbiology" or other tests that are at least as effective as those tests in detecting the infectious agents specified therein, and

1-12-00 (iii) take the non-testing measures specified in the Directive under the headings referred to in subparagraph (ii); and

(*b*) where a donor is rejected as a result of measures taken in accordance with paragraph (*a*),

(i) if none of the donor's semen, whenever donated, has been distributed, destroy all of the donor's semen that is in the processor's possession, or

1-12-00 (ii) if some of the donor's semen, whenever donated, has been distributed, take the measures set out in sections 15 to 18.

1-12-00 (*c*) Repealed by P.C. 2000-1708 of November 30, 2000.

27-7-00 (2) Any test referred to in subparagraph (1)(a)(ii) must meet the requirements set out in clause 3.5.1.1 of the Directive.

Laboratory Controls

10. Every person who processes semen for distribution shall ensure that all surfaces, containers and other objects that come in contact with the semen during processing

(*a*) are sterile or are clean and disposable; and

(*b*) are of a material and type that provide adequate protection against contamination of the semen.

Labelling

11. (1) Every person who processes semen for distribution shall

(*a*) mark on each container of the semen, in indelible ink, an identification code that enables the semen to be linked to the donor and to the date of the donation; and

(*b*) distribute with each container of the semen the processor's name and business address.

(2) Every person who distributes semen shall ensure that each container of the semen is marked with, and accompanied by, the information described in subsection (1).

Records

12. (1) Every person who processes semen for distribution shall maintain the following records in respect of each donor:

1-12-00 (*a*) the date of each donation and the tests, screening and monitoring performed in respect of the donor, the dates and results of those measures and, if necessary, an interpretation of the results;

(*b*) in respect of each donation, the identification code marked on each container of the donor's semen, and the number of containers having that identification code;

(*c*) if the processor is a physician who uses the donor's semen in the performance of assisted conception,

1-12-00 (i) the identification code marked on each container of semen and a means to identify the patient on whom the assisted conception was performed, and

(ii) in the case of semen that is distributed in accordance with a special access authorization, the patient's written consent to the use of the semen;

(*d*) if a container of the donor's semen is distributed for further distribution, the name and business address of the person who received the container and the identification code marked on it;

12-1-00 | (*d*.1) if a container of the donor's semen is distributed in accordance with a special access authorization, a copy of the authorization; and

(*e*) in respect of each container of the donor's semen that the processor destroys, the identification code marked on it and the reason for its destruction.

(2) Every person who processes semen for distribution shall establish and maintain written standard operating procedures to be followed in

(*a*) processing semen; and

(*b*) tracing semen in accordance with sections 15 to 18.

13. Every person who distributes semen processed by another person shall keep the following records in respect of each container of that semen:

(*a*) the name and business address of the processor and the identification code marked on the container;

(*b*) if the distributor received the container of semen from a person other than the processor, the name and business address of that person;

(*c*) in the case of a container of semen that is in the person's possession, other than one for which a special access authorization has been issued, the following evidence that the semen was processed in accordance with the requirements of these Regulations in force at the time the semen was distributed to the person, namely, the date that the semen was donated, the tests performed in respect of the donor, the dates and results of the tests and, if necessary, an interpretation of the results;

(*c*.1) in the case of a container of semen that the person distributed before December 1, 2000, evidence that the semen was processed in accordance with the requirements of these Regulations in force at the time the person distributed the semen;

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(*c*.2) in the case of a container of semen that the person distributes on or after December 1, 2000, other than one for which a special access authorization has been issued, the following evidence that the semen was processed in accordance with the requirements of these Regulations in force at the time the person distributes the semen, namely, the date that the semen was donated, the tests performed in respect of the donor, the dates and results of the tests and, if necessary, an interpretation of the results;

(*c*.3) in the case of a container of semen for which a special access authorization has been issued,
- (i) a copy of the authorization,
- (ii) a copy of the declaration referred to in paragraph 19(2)(i), and
- (iii) the date that the semen was donated, the tests performed in respect of the donor, the dates and results of the tests and, if necessary, an interpretation of the results;

(*d*) if the distributor is a physician who uses the semen in the performance of assisted conception,
- (i) a means to identify the patient on whom the assisted conception was performed, and
- (ii) in the case of semen that is distributed in accordance with a special access authorization, the patient's written consent to the use of the semen;

(*e*) if the container of semen is distributed for further distribution, the name and business address of the person who received it;

(*f*) in respect of each container of semen that the distributor destroys, the reason for its destruction; and

1-12-00 | (*g*) in respect of each container of semen that the processor collects under paragraph 16(2)(c) or (3)(c), the date of its collection.

Tracing of Semen

14. Where a physician who performed assisted conception on a woman has reasonable grounds to believe that an infectious agent was transmitted to the woman through semen used in the performance of the assisted conception, the physician shall, without delay,

(*a*) stop the distribution of all containers of semen in the physician's possession having the same identification codes as that of the semen used for the assisted conception; and

(*b*) provide a written report to each processor of the semen

(i) advising that semen that they processed may be contaminated by an infectious agent, and naming the agent, and
(ii) specifying the identification codes marked on the containers of that semen.

15. (1) Where a processor receives a report under paragraph 14(*b*), or otherwise has reasonable grounds to believe that semen that the processor processed and distributed may be contaminated by an infectious agent, the processor shall, without delay,

(*a*) identify the donors of the semen and quarantine all semen from those donors that is in the processor's possession;

(*b*) use all reasonable means to identify, and locate the business address of, each person who received for further distribution semen obtained from any of those donors;

(*c*) give to each of the following persons a written notice specifying the identification codes marked on the containers of the semen believed to be contaminated, naming the infectious agent and indicating that the semen must be quarantined pending the completion of an investigation or must be destroyed, namely
(i) any person to whom the processor distributed, for further distribution, containers of semen having the identification codes specified in the notice, and
(ii) any other person who the processor believes received, for further distribution, containers of that semen;

(*d*) notify the donors of the semen in writing that an investigation is being conducted to determine whether semen that they donated is contaminated by an infectious agent, and naming the agent; and

(*e*) conduct an investigation to determine whether any of the semen provided by those donors is contaminated by an infectious agent.

(1.1) Despite subsection (1), the processor of semen that has been distributed in accordance with a special access authorization is not required to take the measures specified in that subsection by reason only that

1-12-00 (*a*) a particular infectious agent, other than one referred to in column 1 of the table to subsection 20(1), was not tested for in accordance with the requirements of paragraphs 4(1)(b) and 9(1)(a) during the processing of the semen; or
(*b*) the semen was not processed in accordance with section 10.

(2) Every person who distributed semen that is subject to investigation under paragraph (1)(*e*) shall, at the request of the processor conducting the investigation, provide the name and business address of every person to whom the person distributed the semen for further distribution.

1-12-00 (3) Every processor who conducts an investigation shall provide the Minister with the following information at the following times:

(*a*) within three days after the start of the investigation, the name of the infectious agent with which the semen is believed to be contaminated, the number of donors who donated semen that is believed to be contaminated and the number of containers of semen attributable to each donor; and

(*b*) every 30 days after the start of the investigation, until the final report is provided, an update on the progress made in tracing the semen, including information as to the number of containers used, recovered, quarantined or destroyed, and the number of persons contacted.

*(R) Minor correction

16. (1) Where the results of the investigation demonstrate that all or some of the semen is not contaminated by an infectious agent, the processor

(*a*) shall prepare a list specifying the identification codes marked on the containers of the semen that is not contaminated;

(*b*) shall notify each person referred to in paragraph 15(1)(*c*), in writing, that the containers having the identification codes specified in the list may be distributed; and

(*c*) may distribute the containers in the processor's possession that have the identification codes specified in the list.

(2) Where the results of the investigation demonstrate that all or some of the semen is contaminated by an infectious agent, the processor shall

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(*a*) prepare a list specifying the identification codes marked on the containers of the semen that is contaminated;

(*b*) notify each person referred to in paragraph 15(1)(*c*), in writing, that all quarantined containers having the identification codes specified in the list must be collected by the processor;

(*c*) collect and destroy the containers of semen referred to in paragraph (*b*); and

(*d*) destroy the containers of semen in quarantine under paragraph 15(1)(*a*) that have the identification codes specified in the list.

(3) Where the results of the investigation are inconclusive as to whether all or some of the semen is contaminated by an infectious agent, the processor shall

(*a*) prepare a list specifying the identification codes marked on the containers of that semen;

(*b*) notify each person referred to in paragraph 15(1)(c), in writing, either

(i) that all quarantined containers having the identification codes specified in the list must be destroyed or reserved for special access distribution, or

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(ii) that all quarantined containers having the identification codes specified in the list must be destroyed, reserved for special access distribution or kept in quarantine until collected by the processor;

(*c*) if the person to whom the processor gave a notice under subparagraph (b)(ii) informs the processor that the person has chosen to have the processor collect the containers as proposed in the notice, collect those containers and destroy them or reserve them for special access distribution; and

(*d*) destroy the containers of semen in the processor's possession having the identification codes specified in the list or reserve them for special access distribution.

17. (1) Every person who receives a notice of an investigation from a processor shall

(*a*) quarantine all containers of semen having the identification codes referred to in the notice until the person receives a further notice under section 16; or

(*b*) destroy those containers of semen.

(2) Where the person receives a notice referred to in paragraph 16(1)(*b*), the person may distribute the semen specified in the notice.

(3) Where the person receives a notice referred to in paragraph 16(2)(*b*), the person shall

(*a*) keep in quarantine all containers of the semen having the identification codes referred to in the notice until they are collected by the processor, or destroy them; and

(*b*) provide a written report to the processor as soon as possible indicating, for each identification code referred to in the notice, the number of containers received by the person and the number that were distributed or destroyed.

(4) Where the person receives a notice referred to in paragraph 16(3)(b), the person shall

(*a*) take one of the following actions, namely,

(i) destroy all the containers of the semen in the person's possession having the identification codes referred to in the notice,

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(ii) reserve those containers for special access distribution, or

(iii) in the case of a notice that proposes the collection of those containers, if the person chooses this option, inform the processor in writing of this decision and keep those containers in quarantine until they are collected by the processor; and

(*b*) provide a written report to the processor as soon as possible indicating, for each identification code referred to in the notice, the number of containers received by the person and the number of containers that were distributed, destroyed, reserved for special access distribution or kept in quarantine for collection by the processor.

18. Every processor who conducts an investigation under paragraph 15(1)(*e*) shall, on completion of the investigation,

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(*a*) provide the Minister with a detailed report setting out the results of the investigation, including, where the semen is required to be collected, destroyed or reserved for special access distribution, the disposition of all containers of that semen; and

(*b*) notify in writing the donors of the semen of the results of the investigation.

PART 2

SPECIAL ACCESS

Application

19. (1) If a physician wishes to obtain access to semen that has not been processed in accordance with the requirements of paragraphs 4(1)(b) and 9(1)(a) and section 10 or that has been reserved for special access distribution for use in performing assisted conception on a patient whose needs can not be met using semen that has been processed in accordance with those requirements, the physician shall apply in writing to the Minister for a special access authorization that permits the processor, distributor or importer of the semen or several of those persons to distribute or import for distribution the semen for that purpose.

(2) The application shall contain the following:

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(*a*) the name, business address and business telephone number of the physician;

(*b*) the name and business address of the processor of the requested semen;

(*c*) the name and business address of the distributor from whom the physician obtained or will obtain the semen;

(*d*) the name and business address of the person who is in possession of the semen;

(*e*) in the case of semen that is to be imported, the name and business address of the importer of the semen;

(*f*) the name and address of the health care facility to which the semen is to be shipped;

(*g*) the initials and date of birth of the patient;

(*h*) the number of containers of semen requested and the identification code of each requested container;

(*i*) a declaration signed by the processor or an authorized agent of the processor

(i) certifying that the requested semen has been processed in accordance with section 11,

(ii) certifying that the tests referred to in paragraph 20(1)(b) have been performed in respect of the donor of the requested semen and that the results of the tests were negative, and

(iii) indicating which measures required under paragraphs 4(1)(b) and 9(1)(a) have not been taken and the reasons why they have not been taken;

(*j*) the date that the requested semen was donated and the tests, screening and monitoring performed in respect of the donor of the semen and the dates and results of those measures, including, if necessary, an interpretation of the results;

(k) a statement by the physician that he or she has obtained information from the processor as to whether the requested semen was processed in accordance with section 10;

(l) a statement by the physician indicating that he or she does not have reasonable grounds to believe that an infectious agent may have been transmitted to a woman as a result of assisted conception having been performed on the woman using semen from the same donor as that of the requested semen;

(m) a rationale by the physician that outlines

(i) the reasons that justify the use of the requested semen, having regard to the available information on the safety of the semen and the needs of the patient, and

(ii) the reasons why the needs of the patient cannot be met using semen that has been processed in accordance with the requirements of paragraphs 4(1)(b) and 9(1)(a) and section 10;

(n) a statement by the physician that, in his or her opinion, the use of the requested semen would not pose

(i) a serious risk to the health of the patient, having regard to the available information on the safety of the semen and the health of the patient, or

(ii) a serious risk of transmitting an infectious agent to a child to be conceived from the semen, having regard to the available information on the safety of the semen; and

(o) a statement by the physician that he or she has informed the patient of the risks that the use of the requested semen could pose to the patient and to a child to be conceived from the use of the semen and has obtained the patient's written consent to its use.

(3) The application shall be signed and dated by the physician.

Authorization

20. (1) The Minister shall issue a special access authorization to the processor, distributor or importer referred to in the application made under subsection 19(1), or several of those persons, if

(a) the information and documents required under subsection 19(2) have been provided to the Minister;

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(b) testing for each infectious agent set out in column 1 of the table to this subsection was done using one of the following tests and the result of each test was negative, namely,

(i) a serological test for the applicable marker set out in column 2 of that table performed on a specimen obtained from the donor of the requested semen at least six months after the date that the requested semen was donated,

(ii) another test that is at least as effective as the test specified in subparagraph (i) in detecting that infectious agent, or

(iii) in the case of testing for the Hepatitis B Virus (HBV) in respect of semen that was processed before March 14, 2000, a serological test for the Hepatitis B surface antigen (HBsAg) performed on two specimens obtained from the donor of the requested semen within six months of each other, one of which was obtained on or before the date that the requested semen was donated and one of which was obtained after that date;

(c) the results of any other tests set out in the application pursuant to paragraph 19(2)(j) do not indicate that the semen is contaminated by an infectious agent;

(d) in a case in which a test required under subparagraph 4(1)(b)(ii) or 9(1)(a)(ii) has not been performed in respect of the donor in accordance with the requirements of that provision, it is not possible to correct the irregularity; and

(e) the authorization is not being sought for the purpose of circumventing the processing requirements of Part 1.

TABLE

	COLUMN I	COLUMN 2
ITEM	INFECTIOUS AGENT	INFECTIOUS AGENT MARKER
1.	HIV-1 and HIV-2	Antibody to HIV-1 and HIV-2
2.	Hepatitis C Virus (HCV)	Antibody to HCV
3.	Hepatitis B Virus (HBV)	Antibody to Hepatitis B core antigen (IgG anti-HBcAg)

(2) The authorization shall clearly indicate

(*a*) the number of containers of semen in respect of which the authorization is issued and the identification code of each container;

(*b*) the name and business address of every person who is authorized to distribute the semen;

(*c*) in the case of semen that is to be imported for distribution, the name and business address of the person who is authorized to import the semen;

(*d*) the name and business address of the physician to whom the semen may be distributed;

(*e*) the name and address of the health care facility to which the semen may be shipped;

(*f*) the initials and date of birth of the patient in respect of whom the semen may be used in the performance of assisted conception; and

(*g*) the fact that the semen may only be distributed in accordance with the authorization.

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Documentation

21. (1) Every person who distributes semen for further distribution in accordance with a special access authorization shall ensure that the container of the semen is accompanied by a copy of the authorization.

(2) Every person who imports semen for distribution in accordance with a special access authorization shall ensure that the outer shipping container in which the semen is transported

(*a*) displays clearly, on the outside surface of that container,
(i) an indication that the semen may only be distributed in accordance with the authorization, and
(ii) the name and business address of the processor; and

(*b*) is accompanied by a copy of the authorization.

Interpretation

1. The definitions in this section apply in these Regulations.

"Act" means the *Food and Drugs Act*. (*Loi*)

"active device" means a medical device that depends for its operation on a source of energy other than energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device. (*instrument actif*)

"active diagnostic device" means an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity. (*instrument diagnostique actif*)

"active therapeutic device" means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury. (*instrument thérapeutique actif*)

"bar code" means a unique bar code in the symbology of the Universal Product Code (UPC), the Health Industry Business Communications Council (HIBCC) or the European Article Number (EAN), assigned to a medical device by the manufacturer. (*code à barres*)

"body orifice" means a natural opening or a permanent artificial opening in the body, such as a stoma. (*orifice du corps*)

"central cardiovascular system" means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries. (*système cardiovasculaire central*)

"central nervous system" means the brain, meninges, spinal cord and cerebrospinal fluid. (*système nerveux central*)

"closed-loop system", in respect of a medical device, means a system that enables the device to sense, interpret and treat a medical condition without human intervention. (*système à boucle fermée*)

10-5-05 | "Commissioner of Patents" means the Commissioner of Patents appointed under subsection 4(1) of the *Patent Act*. (*commissaire aux brevets*)

"control number" means a unique series of letters, numbers or symbols, or any combination of these, that is assigned to a medical device by the manufacturer and from which a history of the manufacture, packaging, labelling and distribution of a unit, lot or batch of the device can be determined. (*numéro de contrôle*)

"custom-made device" means a medical device, other than a mass-produced medical device, that

(a) is manufactured in accordance with a health care professional's written direction giving its design characteristics;

(b) differs from medical devices generally available for sale or from a dispenser; and

(c) is

(i) for the sole use of a particular patient of that professional, or

(ii) for use by that professional to meet special needs arising in the course of his or her practice. (*instrument fait sur mesure*)

9-05-02 | "dental material" Repealed by P.C. 2002-792 of May 9, 2002.

"directions for use", in respect of a medical device, means full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects. (*mode d'emploi*)

"dispenser" means a person who is a member of a professional governing body and who is entitled, by virtue of their membership in that body, to manufacture or adapt a medical device in accordance with a health care professional's written directions in order to meet the specific requirements of a patient. (*préparateur*)

10-5-05 | "General Council Decision" has the meaning assigned by subsection 30(6) of the Act. (*décision du Conseil général*)

"genetic testing" means the analysis of DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (*test génétique*)

"health care facility" means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities. (*établissement de santé*)

"health care professional" means a person who is entitled under the laws of a province to provide health services in the province. (*professionnel de la santé*)

"identifier" means a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. (*identificateur*)

"implant" means a medical device that is listed in Schedule 2. (*implant*)

"invasive device" means a medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface. (*instrument effractif*)

"*in vitro* diagnostic device" or "IVDD" means a medical device that is intended to be used *in vitro* for the examination of specimens taken from the body. (*instrument diagnostique in vitro ou IDIV*)

"manufacturer" means a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf. (*fabricant*)

"medical device" means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals. (*instrument médical*)

"medical device family" means a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use. (*famille d'instruments*)

"medical device group" means a medical device comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name. (*ensemble d'instruments*)

"medical device group family" means a collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group. (*famille d'ensembles d'instruments*)

"name of the device", in respect of a medical device, includes any information necessary for the user to identify the device and to distinguish it from similar devices. (*nom de l'instrument*)

"near patient *in vitro* diagnostic device" or "near patient IVDD" means an *in vitro* diagnostic device that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside. (*instrument diagnostique clinique in vitro*)

"objective evidence" means information that can be proved true, based on facts obtained through observation, measurement, testing or other means, as set out in the definition "objective evidence" in section 2.19 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time. (*preuve tangible*)

"person" includes a partnership and an association. (*personne*)

"qualified investigator" means a person who is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care in the province and who is designated, by the ethics committee of the health care facility at which investigational testing is to be conducted, as the person to conduct the testing. (*chercheur compétent*)

29-8-06 | "quality management system certificate" means a valid quality management system certificate described in paragraph 32(2)(f), 3(j) or (4)(p), as applicable, that is issued by a registrar recognized by the Minister under section 32.1. (*certificat de système de gestion de la qualité*)

29-8-06 | "quality system certificate" Repealed by P.C. 2006-804 of August 29, 2006.

"recall", in respect of a medical device that has been sold, means any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device

(a) may be hazardous to health;
(b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or
(c) may not meet the requirements of the Act or these Regulations. (*rappel*)

"safety and effectiveness requirements" means the safety and effectiveness requirements set out in sections 10 to 20. (*exigences en matière de sûreté et d'efficacité*)

"serious deterioration in the sate of health" means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage. (*détérioration grave de l'état de santé*)

"significant change" means a change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to any of the following:

(a) the manufacturing process, facility or equipment;
(b) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;
(c) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and
(d) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device and any change to the period used to establish its expiry data. (*modification importante*)

"surgical or dental instrument" means a reusable medical device that is intended for surgical or dental use, including cutting, drilling, sawing, scraping, clamping, hammering, puncturing, dilating, retracting or clipping, without connection to an active device. (*instrument chirurgical ou dentaire*)

"surgically invasive device" means an invasive device that is intended to enter the body through an artificially created opening that provides access to body structures and fluids. (*instrument effractif chirurgical*)

"system" means a medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name. (*système*)

"test kit" means an *in vitro* diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test. (*trousse d'essai*)

"validation" means confirmation by examination and the provision of objective evidence that the requirements for a specific intended use have been fulfilled, as set out in the definition "validation" in section 2.18 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time. (*validation*)

Application

2. These Regulations apply to

(a) the sale and advertising for sale of a medical device; and
(b) the importation of a medical device for sale or for use on individuals, other than importation for personal use.

3. (1) These Regulations also apply to an *in vitro* diagnostic product that is a drug or that contains a drug, as if the product were an *in vitro* diagnostic device.

(2) Subsection (1) does not apply to a drug listed in Schedule E or F to the Act, in the schedule to Part G or J of the *Food and Drug Regulations*, in the Schedules to the *Controlled Drugs and Substances Act* or in the schedule to the *Narcotic Control Regulations*.

4. Only sections 26 to 31, 37, 70, 75, 80, 86 and 87 apply to a dispenser.

5. These Regulations do not apply to a medical gas piping system that is assembled on site at a health care facility and permanently built into the structure of the facility, if

(a) the system meets the requirements of National Standard of Canada CAN/CSA-Z305.1, *Nonflammable Medical Gas Piping Systems*, as amended from time to time; and
(b) a certificate of compliance with that standard has been issued by a testing agency that meets the requirements of National Standard of Canada CAN/CSA-Z305.4, *Qualification Requirements for Agencies Testing Nonflammable Medical Gas Piping Systems*, as amended from time to time.

Classification of Medical Devices

6. Medical devices are classified into one of Classes I to IV by means of the classification rules set out in Schedule 1, where Class I represents the lowest risk and Class IV represents the highest risk.

7. If a medical device can be classified into more than one class, the class representing the higher risk applies.

PART 1

GENERAL

Application

8. This part applies to medical devices that are not subject to Part 2 or 3.

Manufacturer's Obligations

9. (1) A manufacturer shall ensure that the medical device meets the safety and effectiveness requirements.

(2) A manufacturer shall keep objective evidence to establish that the medical device meets those requirements.

Safety and Effectiveness Requirements

10. A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to

(a) identify the risks inherent in the device;
(b) if the risks can be eliminated, eliminate them;
(c) if the risks cannot be eliminated,
  (i) reduce the risks to the extent possible,
  (ii) provide for protection appropriate to those risks, including the provision of alarms, and
  (iii) provide, with the device, information relative to the risks that remain; and
(d) minimize the hazard from potential failures during the projected useful life of the device.

11. A medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety.

12. A medical device shall perform as intended by the manufacturer and shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented.

13. During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health of safety of a patient, user or other person is adversely affected.

14. The characteristics and performance of a medical device shall not be adversely affected by transport or conditions of storage, taking into account the manufacturer's instructions and information for transport and storage.

15. Reasonable measures shall be taken to ensure that every material used in the manufacture of a medical device shall be compatible with every other material with which it interacts and with material that may come into contact with it in normal use, and shall not pose any undue risk to a patient, user or other person.

16. The design, manufacture and packaging of a medical device shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including

(a) flammability or explosion;
(b) presence of a contaminant or chemical or microbial residue;
(c) radiation;
(d) electrical, mechanical or thermal hazards; and
(e) fluid leaking from or entering into the device.

17. A medical device that is to be sold in a sterile condition shall be manufactured and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated.

18. A medical device that is part of a system shall be compatible with every other component or part of the system with which it interacts and shall not adversely affect the performance of that system.

19. A medical device that performs a measuring function shall be designed to perform that function within tolerance limits that are appropriate for the medical conditions, purposes and uses for which the device is manufactured, sold or represented.

20. If a medical device consists of or contains software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated.

Labelling Requirements

21. (1) No person shall import or sell a medical device unless the device has a label that sets out the following information:

(a) the name of the device;
(b) the name and address of the manufacturer;
(c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(d) in the case of a Class III or IV device, the control number;
(e) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units;
9-05-02 | (f) the word "Sterile", if the manufacturer intends the device to be sold in a sterile condition;
(g) the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;
(h) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use;
(i) the directions for use, unless directions are not required for the device to be used safely and effectively; and
(j) any special storage conditions applicable to the device.

(2) The information required pursuant to subsection (1) shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.

22. (1) Subject to subsection (2), if a medical device is intended to be sold to the general public, the information required by subsection 21(1) shall

(a) be set out on the outside of the package that contains the device; and
(b) be visible under normal conditions of sale.

(2) Where a package that contains a medical device is too small to display all the information in accordance with section 21, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.

23. (1) Subject to subsection (3), the information required by subsection 21(1) shall, as a minimum, be in either English or French.

(2) Subject to subsection (3), where the directions for use are supplied in only one official language at the time of sale, directions for use in the other official language shall be made available by the manufacturer as soon as possible at the request of the purchaser.

9-05-02 | (3) In respect of a medical device to be sold to the general public, the information required by paragraphs 21(1)(a) and (e) to (j) shall, as a minimum, be in both English and French.

Contraceptive Devices - Advertising

9-05-02 | **24.** (1) For the purposes of subsections 3(1) and (2) of the Act and subject to section 27, a condom may be advertised and sold to the general public for the purpose of preventing the transmission of venereal disease if the advertisement and the label of the condom claim only that the condom reduces the risk of transmitting venereal disease.

(2) For the purpose of subsection 3(3) of the Act and subject to section 27, contraceptive devices, other than intrauterine devices, may be advertised to the general public by any means other than by the distribution of samples of the devices door-to-door or through the mail.

Class I Medical Devices

25. (1) If the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that a Class I medical device may not meet the safety and effectiveness requirements, the Minister may request the manufacturer to submit, on or before a specified day, information to enable him or her to determine whether the device meets those requirements.

(2) The Minister may direct the manufacturer to stop the sale of a Class I medical device if

(a) the manufacturer does not comply with a request made pursuant to subsection (1) by the day specified in the request; or
(b) the Minister determines, on the basis of the information submitted pursuant to subsection (1), that the device does not meet the safety and effectiveness requirements.

(3) The Minister may lift the direction to stop the sale if

(a) the manufacturer provides the information requested;
(b) corrective action has been taken to ensure that the medical device satisfies the safety and effectiveness requirements; or
(c) the Minister's determination was unfounded.

Class II, III and IV Medical Devices

Prohibition

26. Subject to section 37, no person shall import or sell a Class II, III or IV medical device unless the manufacturer of the device holds a licence in respect of that device or, if the medical device has been subjected to a change described in section 34, an amended medical device licence.

27. No person shall advertise a Class II, III or IV medical device for the purpose of sale unless

(a) the manufacturer of the device holds a licence in respect of that device or, if the device has been subjected to a change described in section 34, an amended medical device licence; or
(b) the advertisement is placed only in a catalogue that includes a clear and visible warning that the devices advertised in the catalogue may not have been licensed in accordance with Canadian law.

Medical Devices Deemed Licensed

28. If a system is licensed, all of its components or parts that are manufactured by the manufacturer of the system are deemed, for the purposes of its importation, sale or advertisement, to have been licensed.

29. If a test kit is licensed, all of its reagents or articles that are manufactured by the manufacturer of the test kit are deemed, for the purposes of its importation, sale or advertisement, to have been licensed.

30. If a medical device or a medical device group is licensed and forms part of a medical device family or a medical device group family, as the case may be, all other medical devices or medical device groups in the family are deemed to have been licensed.

31. (1) If all the medical devices that form part of a medical device group are licensed, that medical device group is deemed to have been licensed.

(2) If a medical device group is licensed, all the medical devices that form part of the medical device group are deemed, for the purposes of its importation, sale or advertisement, to have been licensed.

Application for a Medical Device Licence

32. (1) An application for a medical device licence shall be submitted to the Minister by the manufacturer of the medical device in a format established by the Minister and shall contain the following:

(a) the name of the device;
(b) the class of the device;
(c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(d) the name and address of the manufacturer as it appears on the device label; and
(e) the name and address of the establishment where the device is being manufactured, if different from the one referred to in paragraph (d).

(2) An application for a Class II medical device licence shall contain, in addition to the information and documents set out in subsection (1), the following:

(a) a description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented;
(b) a list of the standards complied with in the manufacture of the device to satisfy the safety and effectiveness requirements;
(c) an attestation by a senior official of the manufacturer that the manufacturer has objective evidence to establish that the device meets the safety and effectiveness requirements;
(d) an attestation by a senior official of the manufacturer that the device label meets the applicable labelling requirements of these Regulations;
(e) in the case of a near patient *in vitro* diagnostic device, an attestation by a senior official of the manufacturer that investigational testing has been conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use; and
29-8-06 (f) a copy of the quality management system certificate certifying that the quality management system under which the device is manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485:03, *Medical devices – Quality management systems – Requirements for regulatory purposes* .

(3) An application for a Class III medical device licence shall contain, in addition to the information and documents set out in subsection (1), the following:

(a) a description of the device and of the materials used in its manufacture and packaging;
(b) a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;
(c) a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries;
(d) a list of the standards complied with in the design and manufacture of the device to satisfy the safety and effectiveness requirements;
(e) in the case of a device to be sold in a sterile condition, a description of the sterilization method used;
(f) a summary of all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, and the conclusions drawn from those studies by the manufacturer;
(g) a copy of the device label;
(h) in the case of a near patient *in vitro* diagnostic device, a summary of investigational testing conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use;
(i) a bibliography of all published reports dealing with the use, safety and effectiveness of the device; and
29-8-06 (j) a copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485:03, *Medical devices– Quality management systems– Requirements for regulatory purposes.*

(4) An application for a Class IV medical device licence shall contain, in addition to the information and documents set out in subsection (1), the following:

(a) a description of the device and of the materials used in its manufacture and packaging;
(b) a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;
(c) a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries;
(d) a risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted to satisfy the safety and effectiveness requirements;
(e) a quality plan setting out the specific quality practices, resources and sequence of activities relevant to the device;
(f) the specifications of the materials used in the manufacture and packaging of the device;
(g) the manufacturing process of the device;
(h) a list of the standards complied with in the design and manufacture of the device to satisfy the safety and effectiveness requirements;
(i) detailed information on all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, including
  (i) pre-clinical and clinical studies,
  (ii) process validation studies,
  (iii) if appropriate, software validation studies, and
  (iv) literature studies;
(j) in the case of a medical device other than an *in vitro* diagnostic device, manufactured from or incorporating animal or human tissue or their derivative, objective evidence of the biological safety of the device;
(k) in the case of a near patient *in vitro* diagnostic device, detailed information on investigational testing conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use;
(l) a summary of the studies referred to in paragraph (i) and the conclusions drawn from those studies by the manufacturer;
(m) a summary of the investigational testing referred to in paragraph (k) and the conclusions drawn from that testing by the manufacturer;
(n) a bibliography of all published reports dealing with the use, safety and effectiveness of the device;
(o) a copy of the device label; and
29-8-06 (p) a copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485:03, *Medical devices – Quality management systems – Requirements for regulatory purposes.*

Quality Management System Certificate

32.1 The Minister shall recognize a person as a registrar for the purpose of issuing quality management system certificates if the person

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(a) has sufficient training, experience and technical knowledge in the design and manufacture of medical devices and in the effective implementation of quality management systems to determine whether a quality management system satisfies a standard referred to in paragraph 32(2)(f), 3(j) or 4(p); and

(b) conducts quality management system audits in accordance with the applicable guidelines and practices established by the International Organization for Standardization.

32.2 A quality management system certificate is valid for the period, not exceeding three years, specified in it.

32.3 A registrar shall notify the Minister in writing within 15 days after suspending or cancelling a quality management system certificate.

32.4 A registrar shall notify the Minister in writing within 15 days after the expiry of a quality management system certificate if the certificate has not been renewed.

32.5 The Minister may cease to recognize a person as a registrar if the person no longer meets the requirements of section 32.1 or fails to comply with section 32.3 or 32.4.

Foreign Manufacturers

33. (1) If an application for a medical device licence is submitted by a manufacturer of a country other than Canada, the information and documents described in subsections 32(2) to (4) need not be submitted if

(a) the applicant is governed, in that country, by a regulatory authority that is recognized by the Minister; and

(b) the application is accompanied by a certificate of compliance and a supporting summary report, issued by a conformity assessment body of that country that is recognized by the Minister, which certify that the medical device meets the safety and effectiveness requirements.

(2) For the purposes of subsection (1), the Minister may recognize a regulatory authority and a conformity assessment body of a country other than Canada only if it has the ability to determine whether the device meets the safety and effectiveness requirements.

(3) The Minister shall, on request, make available to any interested persons the list of recognized regulatory authorities and conformity assessment bodies of countries other than Canada.

Application for a Medical Device Licence Amendment

34. If the manufacturer proposes to make one or more of the following changes, the manufacturer shall submit to the Minister, in a format established by the Minister, an application for a medical device licence amendment including the information and documents set out in section 32 that are relevant to the change:

(a) in the case of a Class III or IV medical device, a significant change;
(b) a change that would affect the class of the device;
(c) a change in the name of the manufacturer;
(d) a change in the name of the device;
(e) a change in the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(f) in the case of a Class II medical device, a change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented.

Additional Information and Samples

35. (1) If the information and documents submitted in respect of an application for a medical device licence or a medical device licence amendment are insufficient to enable the Minister to determine whether a medical device meets the safety and effectiveness requirements, the Minister may request the manufacturer to submit, on or before a specified day, additional information necessary for making the determination.

(2) In the course of examining the application, the Minister may require the applicant to provide samples of the medical device.

Issuance

36. (1) If the Minister determines that a medical device in respect of which an application is submitted meets the safety and effectiveness requirements, the Minister shall

(a) issue to the manufacturer of the device a medical device licence, in the case of an application for a medical device licence; or
(b) amend the medical device licence, in the case of an application for a medical device licence amendment.

(2) The Minister may set out in a medical device licence terms and conditions respecting

(a) the tests to be performed on a device to ensure that it continues to meet the safety and effectiveness requirements; and
(b) the requirement to submit the results and protocols of any tests performed.

(3) The Minister may amend the terms and conditions of the medical device licence to take into account any new development with respect to the device.

(4) The holder of the medical device licence shall comply with the terms and conditions of the licence.

Lot of *In Vitro* Diagnostic Devices

37. No person shall sell a medical device from a lot of licensed *in vitro* diagnostic devices in respect of which terms and conditions were set out in the licence pursuant to section 36, unless

(a) the results and protocol of any test performed on the device in accordance with those terms and conditions have been provided to the Minister; and
(b) the Minister determines, on the basis of the information received under paragraph (a), that the device continues to meet the safety and effectiveness requirements.

Refusal to Issue

38. (1) The Minister may refuse to issue or amend a medical device licence if

(a) the applicant does not comply with these Regulations or any provisions of the Act relating to medical devices;
(b) the applicant has made a false or misleading statement in the application;
(c) the medical device does not comply with the labelling requirements set out in sections 21 to 23; or
(d) the applicant has not complied with a request for additional information or samples made pursuant to section 35 by the day specified in the request.

(2) The Minister shall refuse to issue or amend a medical device licence if the medical device does not meet the safety and effectiveness requirements or if the information or samples provided pursuant to section 35 are insufficient to enable the Minister to determine whether the medical device meets those requirements.

(3) If the Minister refuses to issue or amend a medical device licence, the Minister shall

(a) notify the applicant in writing of the reasons for the refusal; and
(b) give the applicant an opportunity to be heard.

Additional Information

39. If the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that a licensed medical device may not meet the safety and effectiveness requirements, the Minister may request the manufacturer to submit, on or before a specified day, information or samples to enable the Minister to determine whether the device meets those requirements.

Suspension

40. (1) Subject to subsection (3), the Minister may suspend a medical device licence if the Minister has reasonable grounds to believe that

(a) the licensee has contravened these Regulations or any provision of the Act relating to medical devices;
(b) the licensee has made a false or misleading statement in the application;
(c) the licensee has failed to comply with the terms and conditions of the licence;
(d) the licensee has not complied with a request for information or samples made pursuant to section 39 by the day specified in the request, or the information or samples provided are insufficient to enable the Minister to determine whether the medical device meets the safety and effectiveness requirements;
(e) the medical device no longer meets the safety and effectiveness requirements; or
29-8-06 |
(f) on the basis of information obtained after the device was licensed, the quality management system under which the device has been designed, in the case of a Class III or IV device, or manufactured, assembled, processed, packaged, refurbished or modified, in the case of a Class II, III or IV device, is inadequate to ensure that the device meets its specifications.

(2) Before suspending a medical device licence, the Minister shall consider

(a) the licensee's history of compliance with these Regulations and with the provisions of the Act relating to medical devices; and
(b) the risk that allowing the licence to continue to be in force would constitute for the health or safety of patients, users or other persons.

(3) Subject to section 41, the Minister shall not suspend a medical device licence until

(a) the Minister has sent the licensee a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
(b) if corrective action is required, the time set out in the notice has passed without the action having been taken; and
(c) the licensee has been given an opportunity to be heard in respect of the suspension.

41. (1) The Minister may suspend a medical device licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health or safety of patients, users or other persons, by giving the licensee a notice in writing that states the reason for the suspension.

(2) A licensee may ask the Minister, in writing, that the suspension be reconsidered.

(3) The Minister shall, within 45 days after the date of receiving the request, provide the licensee with an opportunity to be heard.

42. The Minister may reinstate a medical device licence if the situation giving rise to the suspension has been corrected or if the reason for the suspension was unfounded.

Obligation to Inform

43. (1) Every manufacturer of a licensed medical device shall, annually before November 1 and in a form authorized by the Minister, furnish the Minister with a statement signed by the manufacturer or by a person authorized to sign on the manufacturer's behalf

(a) confirming that all the information and documents supplied by the manufacturer with respect to the device are still correct; or
15-5-03 | (b) describing any change to the information and documents supplied by the manufacturer with respect to the device, other than those to be submitted under section 34 or 43.1.

(2) If the manufacturer fails to comply with subsection (1), the Minister may cancel the medical device licence.

(3) If the holder of a medical device licence discontinues the sale of the medical device in Canada, the licensee shall inform the Minister within 30 days after the discontinuance, and the licence shall be cancelled at the time that the Minister is informed.

15-5-03 | **Obligation to Submit Certificate**

29-8-06 | **43.1** Subject to section 34, if a new or modified quality management system certificate is issued in respect of a licensed medical device, the manufacturer of the device shall submit a copy of the certificate to the Minister within 30 days after it is issued.

Application

43.2 Sections 43.3 to 43.6 apply to a medical device in respect of which a manufacturer has applied to the Commissioner of Patents for an authorization under section 21.04 of the *Patent Act* for the purposes of implementing the General Council Decision.

Notices to Commissioner of Patents

43.3 The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.04(3)(b) of the *Patent Act* that the manufacturer's medical device meets the requirements of the Act and these Regulations if

(a) the manufacturer holds a medical device licence in respect of the device issued in accordance with section 36;
(b) the Minister is satisfied that the manufacturer and the device comply with the Act and these Regulations;
(c) the manufacturer has submitted to the Minister a copy of the application filed by the manufacturer with the Commissioner of Patents under section 21.04 of the *Patent Act*;
(d) the manufacturer has submitted to the Minister information regarding the manner in which the mark referred to in paragraph 43.5(1)(a) is applied to all permanent components of the device; and
(e) the manufacturer has submitted to the Minister a sample of the label for the device that includes the information required by paragraph 43.5(1)(b).

43.4 The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.13(b) of the *Patent Act* in the event that the Minister is of the opinion that the manufacturer's medical device referred to in section 43.2 has ceased to meet the requirements of the Act and these Regulations.

Marking and Labelling

43.5 (1) No person shall sell a medical device referred to in section 43.2 unless

(a) the mark "XCL" is displayed on all permanent components of the device; and
(b) the label of the device displays the mark "XCL" followed by the control nunmber referred to in paragraph 21(1)(d) and the words "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA." or "POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA.".

(2) The information required by subsection (1) shall be expressed in a legible, permanent and prominent manner.

Notice to Minister

43.6 The manufacturer of a medical device referred to in section 43.2 shall notify the Minister in writing not less than 15 days prior to commencing the manufacture of the device.

Prohibition

44. (1) No person shall import or sell a medical device unless the person holds an establishment licence.

(2) Subsection (1) does not apply to the importation or sale of a medical device by

(a) a retailer;
(b) a health care facility;
(c) in the case of a Class II, III or IV medical device, the manufacturer of the medical device; or
(d) in the case of a Class I device, the manufacturer of the medical device, if the manufacturer imports or distributes solely through a person who holds an establishment licence.

Application

45. An application for an establishment licence shall be submitted to the Minister in a format established by the Minister and shall contain the following:

(a) the name and address of the establishment;
(b) the name, title and telephone number of the representative of the establishment to contact for any information concerning the application;
(c) a statement as to whether the activity of the establishment is importation or distribution, or both;

(d) the names and addresses of the manufacturers of the devices that are being imported or distributed;
(e) for each manufacturer, the medical specialities, selected from among the specialities established by the Minister, in respect of which the devices are imported or distributed;
(f) for each manufacturer, the classes of the devices that are being imported or distributed;
(g) an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of distribution records, complaint handling and recalls;
(h) if the establishment imports devices, an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of mandatory problem reporting;
(i) if the establishment imports or distributes Class II, III or IV devices, an attestation by a senior official of the establishment that the establishment has documented procedures in place, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect of those devices; and
(j) the address of each building in Canada where the procedures described in paragraphs (g) to (i) are in place.

Issuance

46. (1) If the Minister determines that the application for an establishment licence meets the requirements of section 45, the Minister shall issue to the applicant a licence in respect of the establishment.

(2) An establishment licence shall expire on December 31 of each year.

Refusal

47. (1) The Minister may refuse to issue an establishment licence if the applicant has made a false or misleading statement in the application.

(2) The Minister shall refuse to issue an establishment licence if the Minister has reasonable grounds to believe that issuing such a licence would constitute a risk to the health or safety of patients, users or other persons.

(3) If the Minister refuses to issue an establishment licence, the Minister shall

(a) notify the applicant in writing of the reasons for the refusal; and
(b) give the applicant an opportunity to be heard.

Notification

48. If, following the issuance of an establishment licence, there is a change to any of the information submitted in accordance with paragraph 45(a) or (b), the holder of the establishment licence shall submit the new information to the Minister within 15 days of the change.

Suspension

49. (1) Subject to subsection (3), the Minister may suspend an establishment licence if the Minister has reasonable grounds to believe that

(a) the licensee has contravened these Regulations or any provision of the Act relating to medical devices;
(b) the licensee has made a false or misleading statement in the application; or
(c) failure to suspend the establishment licence would constitute a risk to the health or safety of patients, users or other persons.

(2) Before suspending an establishment licence, the Minister shall consider

(a) the licensee's history of compliance with these Regulations and with the provisions of the Act relating to medical devices; and
(b) the risk that allowing the licence to continue to be in force would constitute for the health or safety of patients, users or other persons.

(3) Subject to section 50, the Minister shall not suspend an establishment licence until

(a) the Minister has sent the licensee a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
(b) if corrective action is required, the time set out in the notice has passed without the action having been taken; and
(c) the licensee has been given an opportunity to be heard in respect of the suspension.

50. (1) The Minister may suspend an establishment licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health or safety of patients, users or other persons, by giving the licensee a notice in writing that states the reason for the suspension.

(2) A licensee may ask the Minister, in writing, that the suspension be reconsidered.

(3) The Minister shall, within 45 days after the date of receiving the request, provide the licensee with an opportunity to be heard.

51. The Minister may reinstate an establishment licence if the situation giving rise to the suspension has been corrected or if the reason for the suspension was unfounded.

Distribution Records

52. (1) The manufacturer, importer and distributor of a medical device shall each maintain a distribution record in respect of each device.

(2) Subsection (1) does not apply to

(a) a retailer; or
(b) a health care facility in respect of a medical device that is distributed for use within that facility.

53. The distribution record shall contain sufficient information to permit complete and rapid withdrawal of the medical device from the market.

54. (1) The distribution record maintained by a manufacturer of an implant shall also contain a record of the information received on the implant registration cards forwarded to the manufacturer from a health care facility pursuant to section 67.

(2) The manufacturer of an implant shall update the information referred to in subsection (1) in accordance with any information received from the health care facility or the patient.

55. The manufacturer, importer and distributor shall retain the distribution record maintained in respect of a medical device for the longer of

(a) the projected useful life of the device, and
(b) two years after the date the device is shipped.

56. Distribution records shall be maintained in a manner that will allow their timely retrieval.

Complaint Handling

57. (1) The manufacturer, importer and distributor of a medical device shall each maintain records of the following:

(a) reported problems relating to the performance characteristics or safety of the device, including any consumer complaints, received by the manufacturer, importer or distributor after the device was first sold in Canada; and
(b) all actions taken by the manufacturer, importer or distributor in response to the problems referred to in paragraph (a).

(2) Subsection (1) does not apply to

(a) a retailer; or
(b) a health care facility in respect of a medical device that is distributed for use within that facility.

58. The manufacturer, importer and distributor of a medical device shall each establish and implement documented procedures that will enable the manufacturer, importer or distributor to carry out

(a) an effective and timely investigation of the problems referred to in paragraph 57(1)(a); and
(b) an effective and timely recall of the device.

Mandatory Problem Reporting

59. (1) Subject to subsection (2), the manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring inside or outside Canada and involving a device that is sold in Canada and that

(a) is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its the directions for use; and
(b) has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur.

(2) The requirement to report an incident that occurs outside Canada does not apply unless the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or unless the regulatory agency has required the manufacture to take corrective action.

60. (1) A preliminary report shall be submitted to the Minister

(a) in respect of an incident that occurs in Canada
  (i) within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or
  (ii) within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur; and
(b) in respect of an incident that occurs outside Canada, as soon as possible after the manufacturer has indicated, to the regulatory agency referred to in paragraph 59(2), the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action.

(2) The preliminary report shall contain the following information:

(a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(b) if the report is made by
  (i) the manufacturer, the name and address of that manufacturer and of any known importer, and the name, title and telephone and facsimile numbers of a representative of the manufacturer to contact for any information concerning the incident, or
  (ii) the importer of the device, the name and address of the importer and of the manufacturer, and the name, title and telephone and facsimile numbers of a representative of the importer to contact for any information concerning the incident;
(c) the date on which the incident came to the attention of the manufacturer or importer;
(d) the details known in respect of the incident, including the date on which the incident occurred and the consequences for the patient, user or other person;
(e) the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer;
(f) the identity of any other medical devices or accessories involved in the incident, if known;
(g) the manufacturer's or importer's preliminary comments with respect to the incident;
(h) the course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report, and
(i) a statement indicating whether a previous report has been made to the Minister with respect to the device and, if so, the date of the report.

61. (1) After the preliminary report is made in accordance with section 60, a final report shall be submitted to the Minister in accordance with the timetable established under paragraph 60(2)(h).

(2) The final report shall contain the following information:

(a) a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died;

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(b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and

(c) any actions taken as a result of the investigation, which may include

(i) increased post-market surveillance of the device,

(ii) corrective and preventive action respecting the design and manufacture of the device, and

(iii) recall of the device.

61.1 (1) Despite subsection 59(1), the manufacturer of a medical device may permit the importer of the device to prepare and submit the preliminary and final reports on the manufacturer's behalf if the information that the manufacturer and importer must include is identical.

(2) The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to prepare and submit the reports on the manufacturer's behalf.

Recall

63. Sections 64 and 65 do not apply to

(a) a retailer; or

(b) a health care facility in respect of a medical device that is distributed for use within that facility.

64. The manufacturer and the importer of a medical device shall, on or before undertaking a recall of the device, each provide the Minister with the following:

(a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

(b) the name and address of the manufacturer and importer, and the name and address of the establishment where the device was manufactured, if different from that of the manufacturer;

(c) the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered;

(d) an evaluation of the risk associated with the defectiveness or possible defectiveness;

(e) the number of affected units of the device that the manufacturer or importer

(i) manufactured in Canada,

(ii) imported into Canada, and

(iii) sold in Canada;

(f) the period during which the affected units of the device were distributed in Canada by the manufacturer or importer;

(g) the name of each person to whom the affected device was sold by the manufacturer or importer and the number of units of the device sold to each person;

(h) a copy of any communication issued with respect to the recall;

(i) the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Minister will be informed of the progress of the recall and the proposed date for its completion;

(j) the proposed action to prevent a recurrence of the problem; and

(k) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the recall.

65. The manufacturer and the importer of a medical device shall, as soon as possible after the completion of a recall, each report to the Minister

(a) the results of the recall; and

(b) the action taken to prevent a recurrence of the problem.

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65.1 (1) Despite sections 64 and 65, the manufacturer of a medical device may permit the importer of the device to prepare and submit, on the manufacturer's behalf, the information and documents with respect to the recall if the information and documents that the manufacturer and importer must submit are identical.

(2) The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to prepare and submit the information and documents with respect to the recall on the manufacturer's behalf.

Implant Registration

66. (1) Subject to section 68, the manufacturer of an implant shall provide, with the implant, two implant registration cards that contain

(a) the name and address of the manufacturer;
(b) the name and address of any person designated by the manufacturer for the collection of implant registration information;
(c) a notice advising the patient that the purpose of the cards is to enable the manufacturer to notify the patient of new information concerning the safety, effectiveness or performance of the implant, and any required corrective action; and
(d) a statement advising the patient to notify the manufacturer of any change of address.

(2) An implant registration card shall be designed for the recording of the following information:

(a) the name of the device, its control number and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(b) the name and address of the health care professional who carried out the implant procedure;
(c) the date on which the device was implanted;
(d) the name and address of the health care facility at which the implant procedure took place; and
(e) the patient's name and address or the identification number used by the health care facility to identify the patient.

(3) The two implant registration cards referred to in subsection (1) shall be printed in both official languages; however, the manufacturer may choose to provide four cards, two in English and two in French.

67. (1) Subject to subsection (2), a member of the staff of the health care facility where an implant procedure takes place shall, as soon as possible after the completion of the procedure, enter the information required by subsection 66(2) on each implant registration card, give one card to the implant patient and forward one card to the manufacturer of the implant or the person designated pursuant to paragraph 66(1)(b).

(2) The patient's name and address shall not be entered on the implant registration card forwarded to the manufacturer or person designated pursuant to paragraph 66(1)(b) except with the patient's written consent.

(3) The health care facility, the manufacturer or the person designated pursuant to paragraph 66(1)(b) shall not disclose the patient's name or address, or any information that might identify the patient, unless the disclosure is required by law.

68. (1) The manufacturer of an implant may apply in writing to the Minister for authorization to use an implant registration method other than the implant registration cards described in section 66.

(2) The Minister shall authorize the use of the implant registration method proposed in the application referred to in subsection (1) if the Minister determines that the method will enable the manufacturer to achieve the purpose set out in paragraph 66(1)(c) as effectively as the use of implant registration cards.

(3) Where an authorization has been granted pursuant to subsection (2), the manufacturer shall implement the alternative implant registration method, and sections 66 and 67 shall apply with such modifications as are necessary.

PART 2

CUSTOM-MADE DEVICES AND MEDICAL DEVICES TO BE IMPORTED OR SOLD FOR SPECIAL ACCESS

Application

69. (1) This Part applies to custom-made devices and medical devices that are to be imported or sold for special access.

(2) In this Part, "special access" means access to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable.

General

70. No person shall import or sell a Class III or IV custom-made device or a medical device for special access unless the Minister has issued an authorization for its sale or importation.

Authorization

71. (1) If a health care professional wishes to obtain a medical device referred to in section 70, the professional shall apply to the Minister for an authorization that would permit the manufacturer or importer of the device to sell, or to import and sell, the device to that professional.

(2) The application shall contain the following:

(a) the name of the device, its class and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(b) the number of units required;
(c) the name and address of the manufacturer or importer;
(d) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the device;
(e) the diagnosis, treatment or prevention for which the device is required;
(f) a statement that sets out
  (i) the reasons the device was chosen for the diagnosis, treatment or prevention,
  (ii) the risks and benefits that are associated with its use, and
  (iii) the reasons the diagnosis, treatment or prevention could not be accomplished using a licensed device that is available for sale in Canada;
(g) the name and address of each health care facility at which the device is to be used by that professional;
(h) the known safety and effectiveness information in respect of the device;
(i) a written undertaking by the health care professional that the professional will inform the patient for whom the device is intended of the risks and benefits associated with its use;
(j) the directions for use, unless directions are not required for the device to be used safely and effectively; and
(k) in the case of a custom-made device, a copy of the health care professional's written direction to the manufacturer giving the design characteristics of the device.

72. (1) The Minister shall issue an authorization referred to in subsection 71(1) to a manufacturer or importer if the Minister determines that

(a) the benefits that may be obtained by the patient through the use of the device outweigh the risks associated with its use;
(b) the health or safety of patients, users or other persons will not be unduly affected;
(c) a licensed device that would adequately meet the requirements of the patient is not available in Canada; and
(d) the authorization is not being used by the manufacturer or importer to circumvent the requirements of Part 1.

(2) The authorization issued under subsection (1) shall specify

(a) the number of units of the device authorized to be imported;
(b) the number of units of the device authorized to be sold; and
(c) the name of the health care professional to whom the manufacturer or importer may sell the device.

Additional Information

73. If the information and documents submitted in respect of an application made pursuant to section 71 are insufficient to enable the Minister to determine whether the conditions set out in subsection 72(1) have been met, the manufacturer, importer or health care professional shall, at the request of the Minister, submit any further information relevant to the application that the Minister may request.

74. The Minister may, in respect of an authorization that has been issued,

(a) request the manufacturer, importer or health care professional to submit information in respect of the device if the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that the device for which the authorization has been issued no longer meets the conditions set out in subsection 72(1); and

(b) issue a written cancellation of the authorization, giving reasons, if

(i) the Minister determines that the conditions set out in subsection 72(1) are no longer met, or

(ii) the information referred to in paragraph (a) has not been submitted.

Labelling

75. No person shall import or sell a medical device in respect of which an authorization has been issued pursuant to section 72, or a Class I or II custom-made device, unless the device has a label that

(a) sets out the name of the manufacturer;

(b) sets out the name of the device; and

(c) specifies whether the device is a custom-made device or is being imported or sold for special access.

Distribution Records

76. The manufacturer or importer of a medical device in respect of which an authorization has been issued pursuant to section 72 shall maintain a distribution record in respect of the device in accordance with sections 52 to 56.

Reporting an Incident

77. The health care professional referred to in subsection 71(1) shall, within 72 hours after the occurrence of an incident described in section 59 involving a medical device for which an authorization has been issued pursuant to section 72, report the incident to the Minister and to the manufacturer or importer of the device, and specify the nature of the incident and the circumstances surrounding it.

Implant Registration

9-05-02 | **78.** Sections 66 to 68 apply in respect of an implant that is imported or sold for special access.

PART 3

MEDICAL DEVICES FOR INVESTIGATIONAL TESTING INVOLVING HUMAN SUBJECTS

Application

79. This Part applies to medical devices that are to be imported or sold for investigational testing involving human subjects.

General

80. (1) Subject to subsections (2) and (3), no person shall import or sell a medical device for investigational testing.

(2) A manufacturer or importer of a Class II, III or IV medical device may sell the device to a qualified investigator for the purpose of conducting investigational testing if the manufacturer or importer holds an authorization issued under subsection 83(1) and possesses records that contain all the information and documents required by section 81.

(3) A manufacturer or importer of a Class I medical device may sell the device to a qualified investigator for the purpose of conducting investigational testing if the manufacturer or importer possesses records that contain all the information and documents required by section 81.

Records

81. The records referred to in section 80 shall contain the following:

(a) the name, address and telephone number of the manufacturer and the importer of the device;
(b) the name of the device, its class and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(c) a description of the device and of the materials used in its manufacture and packaging;
(d) a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;
(e) a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries;
(f) a risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted for the purposes of conducting investigational testing of the device, including, as appropriate,
  (i) the results of any previous research, testing and studies conducted with respect to the device,
  (ii) a description of the methods currently used to diagnose or treat the medical condition in respect of which the investigational testing is being proposed, and
  (iii) information respecting any cautions, warnings, contra-indications and possible adverse effects associated with the use of the device;
(g) the names of all the qualified investigators to whom the device is proposed to be sold and their qualifications, including their training and experience;
(h) the name and address of each institution at which the investigational testing is proposed to be conducted and, in the case of a Class III or IV device, written approval from the institution indicating that the investigational testing may be carried out there;
(i) a protocol of the proposed investigational testing, including the number of units of the device proposed to be used for the testing, the hypothesis for and objective of the testing, the period of time during which the testing will be carried out and a copy of the patient consent form;
(j) a copy of the device label; and
(k) a written undertaking from each qualified investigator to
  (i) conduct the investigational testing in accordance with the protocol provided by the manufacturer;
  (ii) inform a patient who is to be diagnosed or treated using the device of any risks and benefits associated with its use, and obtain the patient's written consent for its use,
  (iii) not use the device or permit it to be used for any purpose other than the investigational testing specified in the protocol,
  (iv) not permit the device to be used by any other person except under the direction of the qualified investigator, and
  (v) in the event of an incident described in section 59, report the incident and the circumstances surrounding it to the Minister and to the manufacturer or importer of the device within 72 hours after it comes to the attention of the qualified investigator.

Authorization

82. An application for an authorization referred to in subsection 80(2) shall be made in writing to the Minister and shall contain

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(a) in the case of a Class II medical device or a Class III or IV *in vitro* diagnostic device that is not used for patient management, not including a near-patient *in vitro* diagnostic device, the information set out in paragraphs 81(a), (b) and (h) to (j); and
(b) in the case of a Class III or IV medical device that is not covered by paragraph (a), the information and documents set out in section 81.

83. (1) The Minister shall issue an authorization referred to in subsection 80(2) to a manufacturer or importer if the Minister determines that

(a) the device can be used for investigational testing without seriously endangering the life, health or safety of patients, users or other persons;
(b) the investigational testing is not contrary to the best interests of patients on whom the testing will be conducted; and
(c) the objective of the testing will be achieved.

(2) The authorization referred to subsection (1) shall specify

(a) the name of any qualified investigator to whom the device may be sold;
(b) the type of diagnosis or treatment for which the device may be sold;
(c) the number of units of the device that are authorized to be sold; and
(d) the protocol according to which the investigational testing is to be conducted.

Additional Information

84. If the information and documents submitted in respect of an application made pursuant to section 82 are insufficient to enable the Minister to determine whether the conditions set out in subsection 83(1) have been met, the manufacturer or importer shall, at the request of the Minister, submit any further information relevant to the application that the Minister may request.

85. (1) The Minister may, in respect of a medical device in relation to which investigational testing is being conducted, request the manufacturer or importer of the device to submit information in respect of the testing if the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that one of the following conditions may exist:

(a) the testing seriously endangers the life, health or safety of patients, users or other persons;
(b) the testing is contrary to the best interests of patients on whom the testing is being conducted;
(c) the objective of the testing will not be achieved;
(d) the qualified investigator who is conducting the testing is not respecting the undertaking required by paragraph 81(k); or
(e) the information submitted in respect of the testing is false or misleading.

(2) If the information requested pursuant to subsection (1) is not submitted, or if it is submitted and the Minister determines after reviewing it that a condition identified in that subsection exists, the Minister may, by written notice giving reasons,

(a) in the case of a Class I device, direct the manufacturer or importer of the device to stop selling the device to any qualified investigator named in the notice; or
(b) in the case of a Class II, III or IV device, cancel the authorization referred to in subsection 83(1), in whole or in part.

Labelling

86. No person shall import or sell a medical device for investigational testing unless the device has a label that sets out

(a) the name of the manufacturer;
(b) the name of the device;
(c) the statements "Investigational Device" and "Instrument de recherche", or any other statement, in English and French, that conveys that meaning;
(d) the statements "To Be Used by Qualified Investigators Only" and "Réservé uniquement à l'usage de chercheurs compétents", or any other statement, in English and French, that conveys that meaning; and
(e) in the case of an IVDD, the statements "The performance specifications of this device have not been established" and "Les spécifications de rendement de l'instrument n'ont pas été établies", or any other statement, in English and French, that conveys that meaning.

Advertising

87. No person shall advertise a medical device that is the subject of investigational testing unless

(a) that person holds an authorization issued under subsection 83(1) to sell or import the device; and
(b) the advertisement clearly indicates that the device is the subject of investigational testing, and the purpose of the investigational testing.

Other Requirements

9-05-02 | **88.** The requirements set out in the following provisions apply to medical devices to which this Part applies:

(a) sections 52 to 56 with respect to distribution records;
(b) sections 57 and 58 with respect to complaint handling;
9-05-02 | (c) sections 59 to 61.1 with respect to mandatory problem reporting;
(d) sections 63 to 65.1 with respect to recalls; and
(e) sections 66 to 68 with respect to implant registration.

PART 4

EXPORT CERTIFICATES

89. (1) For the purposes of section 37 of the Act, Schedule 3 sets out the form to be used for an export certificate for medical devices.

(2) The export certificate shall be signed and dated by

(a) where the exporter of the device is a corporation,
  (i) the exporter's senior executive officer in Canada,
  (ii) the exporter's senior regulatory officer in Canada, or
  (iii) the authorized agent of the person referred to in subparagraph (i) or (ii); or
(b) where the exporter of the device is an individual,
  (i) the exporter, or
  (ii) the exporter's authorized agent.

90. No person shall sign an export certificate that is false or misleading or that contains omissions that may affect its accuracy and completeness.

91. The exporter of a device shall maintain, at their principal place of business in Canada, records that contain the completed export certificates and shall, when requested to do so by an inspector, submit the export certificates for examination.

92. The exporter of a device shall retain the export certificate for a period of not less than five years after the date of export.

PART 5

TRANSITIONAL PROVISIONS, REPEAL AND COMING INTO FORCE

Transitional Provisions

93. For the purposes of sections 94 and 95, "old regulations" means the *Medical Devices Regulations*, C.R.C., c. 871, and "Director" has the meaning assigned to it by those regulations.

94. (1) Subject to subsection (2), if an application for a notice of compliance has been submitted with respect to a medical device pursuant to Part V of the old regulations but has not been processed by the Director as of June 30, 1998, an application for a medical device licence shall be made pursuant to these Regulations.

(2) For the purposes of an application for a medical device licence, the information and documents required by paragraphs 32(2)(a) to (e), (3)(a) to (i) or (4)(a) to (o) are deemed to have been submitted if a notice of compliance with respect to the device has been issued under the old regulations.

95. (1) A medical device that, on June 30, 1998, is being sold in Canada pursuant to the old regulations is not required to be licensed until February 1, 1999, if,

(a) in the case of a device that is subject to Part V of the old regulations, the manufacturer
  (i) has a notice of compliance in respect of the device that is in effect on June 30, 1998, or
  (ii) does not have a notice of compliance in respect of the device that is in effect on June 30, 1998, but has met, during the period beginning on October 8, 1982, and ending on March 31, 1983, the requirements for device notification pursuant to Part II of the old regulations in respect of the device; and

(b) in the case of a device that is not subject to Part V of the old regulations, the manufacturer has, by June 30, 1998, furnished the Director with the notification required in subsection 24(1) of the old regulations in respect of the device.

(2) If an initial application for licensing of a medical device that is referred to in subsection (1) is submitted before February 1, 1999, the information and documents required by paragraphs 32(2)(a) to (e), (3)(a) to (i) or (4)(a) to (o) are deemed to have been submitted if

(a) in the case of a device that is subject to Part V of the old regulations, the manufacturer
  (i) has a notice of compliance in respect of the device that is in effect on June 30, 1998, or
  (ii) does not have a notice of compliance that is in effect on June 30, 1998, in respect of the device, but has met, during the period beginning on October 8, 1982, and ending on March 31, 1983, the requirements for device notification pursuant to Part II of the old regulations in respect of the device;

(b) in the case of a device that is not subject to Part V of the old regulations, the manufacturer has, by June 30, 1998, furnished the Director with the notification required in subsection 24(1) of the old regulations in respect of the device.

(3) Subsections (1) and (2) cease to apply in respect of a medical device if a change described in section 34 is made in respect of the device or if the notice of compliance is suspended or cancelled under section 40 of the old regulations.

(4) For the purposes of this section, a notice of compliance may be suspended or cancelled under section 40 of the old regulations as if that section were still in force.

Repeal

96. The *Medical Devices Regulations* are repealed.

Coming into Force

97. (1) Subject to subsections (2) to (5), these Regulations come into force on July 1, 1998.

(2) Section 32, except paragraphs (2)(f), (3)(j) and (4)(p), comes into force

(a) in the case of a medical device referred to in section 94 or 95, on September 1, 1998;
(b) in the case of any other medical device, on July 1, 1998.

14-6-01 | (3) Paragraphs 32(2)(f), (3)(j) and (4)(p) come into force on January 1, 2003.

(4) Sections 43 and 44 come into force on January 1, 1999.

(5) Sections 45 to 51 come into force on November 1, 1998.

*(R) Minor correction

SCHEDULE 1

(Section 6)

CLASSIFICATION RULES FOR MEDICAL DEVICES

PART 1

MEDICAL DEVICES OTHER THAN *IN VITRO* DIAGNOSTIC DEVICES

Invasive Devices

Rule 1:

(1) Subject to subrules (2) and (3), all surgically invasive devices are classified as Class II.

(2) A surgically invasive device that is intended to diagnose, monitor, control or correct a defect of the central cardiovascular system or the central nervous system or of a fetus in utero is classified as Class IV.

(3) A surgically invasive device that is intended to be absorbed by the body, or that is normally intended to remain in the body for at least 30 consecutive days, is classified as Class III.

Rule 2:

(1) Subject to subrules (2) to (4), all invasive devices that penetrate the body through a body orifice or that come into contact with the surface of the eye are classified as Class II.

(2) A device described in subrule (1) that is intended to be placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum is classified as Class I.

(3) A device described in subrule (1) that is normally intended to remain in the body or in contact with the surface of the eye for at least 30 consecutive days is classified as Class III.

(4) A device described in subrule (1) that is intended to be represented as preventing the transmission of infectious agents during sexual activities or reducing the risk thereof is classified as Class III.

Rule 3:

Despite rules 1 and 2

(a) all denture materials and orthodontic appliances, and their accessories, are classified as Class II;
(b) all surgical or dental instruments are classified as Class I; and
(c) all latex condoms are classified as Class II.

Non-invasive Devices

Rule 4:

(1) Subject to subrule (2), all non-invasive devices that are intended to come into contact with injured skin are classified as Class II.

(2) A device described in subrule (1) that is intended to be used as a mechanical barrier, for compression or for absorption of exudations, is classified as Class I.

Rule 5:

A non-invasive device intended for channelling or storing gases, liquids, tissues or body fluids for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class II.

Rule 6:

(1) Subject to subrules (2) and (3), a non-invasive device intended for modifying the biological or chemical composition of blood or other body fluids, or liquids, for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class III.

(2) A device described in subrule (1) whose characteristics are such that the modification process may introduce a foreign substance into the body that is potentially hazardous, taking into account the nature and quantity of the substance, is classified as Class IV.

(3) A device described in subrule (1) that accomplishes the modification by centrifugation, gravity filtration or the exchange of gas or heat is classified as Class II.

Rule 7:

(1) Subject to subrule (2), all other non-invasive devices are classified as Class I.

(2) A device described in subrule (1) is classified as Class II if it is intended

(a) to act as a calibrator, tester or quality control support to another medical device; or
(b) to be connected to an active device that is classified as Class II, III or IV.

Active Devices

Rule 8:

(1) Subject to subrules (2) and (3), an active device intended to emit ionizing radiation, including any device or software intended to control or monitor such a device or directly influence its performance, is classified as Class III.

(2) A device described in subrule (1) that is intended to be used in radiographic mode is classified as Class II.

(3) Despite subrule (2), an active device that is intended to be used for mammographies is classified as Class III.

Rule 9:

(1) Subject to subrules (2) and (3), an active therapeutic device, including any dedicated software, intended to be used to administer or withdraw energy to or from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.

(3) A device described in subrule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

Rule 10:

(1) Subject to subrule (2), an active diagnostic device, including any dedicated software, that supplies energy for the purpose of imaging or monitoring physiological processes is classified as Class II.

(2) A device described in subrule (1) that is intended to be used to monitor, assess or diagnose a disease, a disorder, an abnormal physical state or a pregnancy, if erroneous readings could result in immediate danger, is classified as Class III.

Rule 11:

(1) Subject to subrules (2) and (3), an active device, including any dedicated software, intended to administer drugs, body fluids or other substances to the body or withdraw them from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the nature of the substance involved and the part of the body concerned, the device is classified as Class III.

(3) A device described in subrule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

Rule 12:

Any other active device is classified as Class I.

Special Rules

Rule 13:

A medical device that is intended to be used for

(a) disinfecting or sterilizing blood, tissues or organs that are intended for transfusion or transplantation is classified as Class IV; and
(b) disinfecting or sterilizing a medical device is classified as Class II.

Rule 14:

(1) Subject to subrule (2), any medical device manufactured from or incorporating non-viable or viable animal or human tissue or their derivatives, or a product produced through the use of recombinant DNA technology, is classified as Class IV.

(2) A device described in subrule (1) that is intended to come into contact with intact skin only is classified as Class I.

Rule 15:

Any medical device that is a material intended to be sold to a health care professional or dispenser for the specific purpose of configuration or arrangement into a mould or shape to meet the needs of an individual is classified in the class that applies to the finished medical device.

Rule 16:

Despite rules 1 to 15, a medical device set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

TABLE

Item	Column 1 Medical device	Column 2 Class
1.	Breast implants	IV
2.	Tissue expanders for breast reconstruction and augmentation	IV

PART 2

IN VITRO DIAGNOSTIC DEVICES

Use with respect to Transmissible Agents

Rule 1:

An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, tissues or organs to assess their suitability for transfusion or transplantation is classified as Class IV.

Rule 2:

An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent is classified as Class II, unless

(a) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease if there is a risk of propagation in the Canadian population, in which case it is classified as Class IV; or
(b) it falls into one of the following categories, in which case it is classified as Class III:
  (i) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a serious disease where there is a risk of propagation in the Canadian population,
  (ii) it is intended to be used to detect the presence of, or exposure to, a sexually transmitted agent,
  (iii) it is intended to be used to detect the presence of an infectious agent in cerebrospinal fluid or blood, or
  (iv) there is a risk that an erroneous result would cause death or severe disability to the individual being tested, or to the individual's offspring.

Rule 3:

An IVDD that is intended to be used for patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class III:

(a) it is intended to be used for the management of patients suffering from a life-threatening disease; or
(b) there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient.

Other Uses

Rule 4:

An IVDD that is not subject to rules 1 to 3 and that is intended to be used in diagnosis or patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class III:

(a) it is intended to be used in screening for or in the diagnosis of cancer;
(b) it is intended to be used for genetic testing;
(c) it is intended to be used in screening for congenital disorders in the fetus;
(d) there is a risk that an erroneous diagnostic result would cause death or severe disability to the patient being tested or to that patient's offspring;
(e) it is intended to be used for disease staging; or
(f) it is intended to be used to monitor levels of drugs, substances or biological components, if there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient.

Rule 5:

An IVDD that is intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, tissue or organs that are intended for transfusion or transplantation is classified as Class III.

Special Rules

Rule 6:

A near patient IVDD is classified as Class III.

Rule 7:

In cases where an IVDD, including its analyzers, reagents and software, is intended to be used with another IVDD, the class of both IVDDs will be that of the IVDD in the class representing the higher risk.

Rule 8:

If rules 1 to 7 do not apply, all other IVDDs are classified as Class I.

Rule 9:

Despite rules 1 to 8, an IVDD set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

TABLE

Item	Column 1 IVDD	Column 2 Class
1.	Near patient *in vitro* diagnostic device for the detection of pregnancy or for fertility testing	II
2.	Near patient *in vitro* diagnostic device for determining cholesterol level	II
3.	Microbiological media used to identify or infer the identity of a microorganism	I
4.	IVDD used to identify or infer the identity of a cultured microorganism	I

SCHEDULE 2
(Section 1)

IMPLANTS

1. Heart valve

2. Annuloplasty ring

3. Active implantable device systems
   (a) all models of implantable pacemakers and leads;
   (b) all models of implantable defibrillators and leads;
   (c) artificial heart;
   (d) implantable ventricular support system; and
   (e) implantable drug infusion system

4. Devices of human origin
   (a) human dura mater; and
   (b) wound covering containing human cells

SCHEDULE 3
(Section 89)

EXPORT CERTIFICATE FOR MEDICAL DEVICES

UNDER THE Medical Devices Regulations

I, _____, certify that I have knowledge of all matters contained in this certificate and that

1. I am (check applicable box)

(a) where the medical device described in this certificate is exported by a corporation

- ☐ the exporter's senior executive officer;
- ☐ the exporter's senior regulatory officer;
- ☐ the authorized agent of the exporter's senior executive officer; or
- ☐ the authorized agent of the exporter's senior regulatory officer; and

(b) where the medical device described in this certificate is exported by an individual

- ☐ the exporter; or
- ☐ the exporter's authorized agent.

_____,

(State name and address of exporter or, if a corporation, name and address of principal place of business in Canada).

2. On the ____ day of _____, a package containing _____

_____

(description of device, including serial number, model name, lot number and quantity, as applicable; if additional space required, attach as Appendix "A")

is/will be consigned to _____

(name and address of consignee).

3. The package is marked in distinct overprinting with the word "Export" or "Exportation".

4. The medical device was not manufactured for consumption in Canada.

5. The medical device is not sold for consumption in Canada.

6. The package and its contents do not contravene any known requirement of the law of the country of

_____

(state country of consignee).

7. All relevant information is contained in this certificate and no relevant information has been knowingly withheld.

_____
Signature

_____
Position title

_____
Date

*(R) Minor correction

Interpretation

1. (1) The definitions in this section apply in these Regulations.

"**Act**" means the *Food and Drugs Act*. (*Loi*)

"**adverse reaction**" means a noxious and unintended response to a natural health product that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function. (*réaction indésirable*)

"**brand name**" means a name in English or French, whether or not it includes the name of a manufacturer, corporation, partnership or individual

(a) that is used to distinguish the natural health product; and

(b) under which a natural health product is sold or advertised. (*marque nominative*)

"**case report**" means a detailed record of all relevant data associated with the use of a natural health product in a subject. (*fiche d'observation*)

"**Compendium**" means the *Compendium of Monographs* published by the Department of Health and as amended from time to time. (*Compendium*)

"**distributor**" means a person who sells a natural health product to another person for the purpose of further sale by that other person. (*distributeur*)

"**expiry date**" means the earlier of

(a) the date, expressed at minimum as a year and month, up to and including which a natural health product maintains its purity and physical characteristics and its medicinal ingredients maintain their quantity per dosage unit and their potency, and

(b) the date, expressed at minimum as a year and month, after which the manufacturer recommends that the natural health product should not be used. (*date limite d'utilisation*)

"**immediate container**" means the container that is in direct contact with a natural health product. (*contenant immédiat*)

"**importer**" means a person who imports a natural health product into Canada for the purpose of sale. (*importateur*)

"**inner label**" means the label on or affixed to an immediate container of a natural health product. (*étiquette intérieure*)

"**lot number**" means any combination of letters, figures, or both, by which a natural health product can be traced in manufacture and identified in distribution. (*numéro de lot*)

"**manufacturer**" means a person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a natural health product for the purpose of sale to that patient. (*fabricant*)

"**natural health product**" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

(b) restoring or correcting organic functions in humans; or

(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2. (*produit de santé naturel*)

"**outer label**" means the label on or affixed to the outside of a package of a natural health product. (*étiquette extérieure*)

"**principal display panel**" has the same meaning as in the *Consumer Packaging and Labelling Regulations*. (*espace principal*)

"**probiotic**" means a monoculture or mixed-culture of live micro-organisms that benefit the microbiota indigenous to humans. (*probiotique*)

"**proper name**" means, in respect of an ingredient of a natural health product, one of the following:
(a) if the ingredient is a vitamin, the name for that vitamin set out in item 3 of Schedule 1;
(b) if the ingredient is a plant or a plant material, an alga, a bacterium, a fungus, a non-human animal material or a probiotic, the Latin nomenclature of its genus and, if any, its specific epithet; and
(c) if the ingredient is other than one described in paragraphs (a) or (b), the chemical name of the ingredient. (*nom propre*)

"**recommended conditions of use**" means, in respect of a natural health product,
(a) its recommended use or purpose;
(b) its dosage form;
(c) its recommended route of administration;
(d) its recommended dose;
(e) its recommended duration of use, if any; and
(f) its risk information, including any cautions, warnings, contra-indications or known adverse reactions associated with its use. (*condition d'utilisation recommandées*)

"**security package** " means a package having a security feature that provides reasonable assurance to consumers that the package has not been opened prior to purchase. (*emballage de sécurité*)

"**serious adverse reaction**" means a noxious and unintended response to a natural health product that occurs at any dose and that requires in-patient hospitalization or a prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death. (*réaction indésirable grave*)

"**serious unexpected adverse reaction**" means a serious adverse reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the natural health product. (*réaction indésirable grave et imprévu*)

"**specifications**" means a description of a natural health product that contains the information described in subsection 44(2). (*spécifications*)

(2) Subject to subsection (3), the words and expressions used in the provisions of the *Food and Drug Regulations* that are incorporated by reference by these Regulations shall have the meanings assigned to them by these Regulations, but if no meanings are assigned, they shall have any meaning assigned to them by the *Food and Drug Regulations*.

(3) The word "manufacturer" in the provisions of the *Food and Drug Regulations* that are incorporated by reference by these Regulations shall have the meaning assigned to it by the *Food and Drug Regulations*.

Application

2. (1) These Regulations apply to

(a) the sale of natural health products;
(b) the manufacture, packaging, labelling and importation for sale of natural health products;
(c) the distribution of natural health products; and
(d) the storage of natural health products for the purposes of any of the activities referred to in paragraphs (b) and (c).

(2) For the purposes of these Regulations, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the *Food and Drug Regulations*, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of those Regulations.

3. Except where otherwise indicated in these Regulations, the provisions of the *Food and Drug Regulations* do not apply to natural health products.

PART 1

PRODUCT LICENCES

Prohibition

4. (1) Subject to subsections (2) and (3), no person shall sell a natural health product unless a product licence is issued in respect of the natural health product.

(2) No product licence holder, manufacturer, importer or distributor of a natural health product for which a product licence is issued shall sell the natural health product during any period that the sale of that natural health product is directed to be stopped under section 17.

(3) No person shall sell a natural health product for which a product licence is issued

(a) during the period of any suspension of the licence under section 18 or 19; or

(b) after cancellation of the licence under paragraph 20(b).

Licence Application

5. An application for a product licence shall be submitted to the Minister and shall contain the following information and documents:

(a) the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant;

(b) if the address submitted under paragraph (a) is not a Canadian address, the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant's representative in Canada to whom notices may be sent;

(c) for each medicinal ingredient of the natural health product,

(i) its proper name and its common name,

(ii) its quantity per dosage unit,

(iii) its potency, if a representation relating to its potency is to be shown on any label of the natural health product,

(iv) a description of its source material, and

(v) a statement indicating whether it is synthetically manufactured;

(d) a qualitative list of the non-medicinal ingredients that are proposed for the natural health product and for each ingredient listed, a statement that indicates the purpose of the ingredient;

(e) each brand name under which the natural health product is proposed to be sold;

(f) the recommended conditions of use for the natural health product;

(g) information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use;

(h) the text of each label that is proposed to be used in conjunction with the natural health product;

(i) a copy of the specifications to which the natural health product will comply; and

(j) one of the following attestations, namely,

(i) if the natural health product is imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3, or

(ii) if the natural health product is not imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, distributed and stored in accordance with requirements set out in Part 3.

Sixty-Day Disposition

6. (1) Subject to subsection (2), the Minister shall dispose of an application submitted under section 5 within 60 days after the day on which it is submitted if, in support of the application, the only information submitted by the applicant under paragraph 5(g) is that which is

(a) in the case of an application respecting a natural health product that has only one medicinal ingredient, contained in a monograph for that medicinal ingredient in the Compendium; and
(b) in the case of an application respecting a natural health product that has more than one medicinal ingredient, contained in a monograph for that combination of medicinal ingredients in the Compendium.

(2) If the Minister requests that additional information or samples be submitted under section 15, the 60-day period referred to in subsection (1) does not include the number of days beginning on the day on which the request is made and ending on the day on which the additional information or samples are received.

(3) For the purposes of this section, the Minister disposes of an application on the earlier of the day on which

(a) the licence is issued in accordance with section 7; and
(b) the applicant is sent a notice under subsection 9(1).

Issuance and Amendment

7. The Minister shall issue or amend a product licence if

(a) the applicant submits an application to the Minister that is in accordance with section 5 or subsection 11(2), as the case may be;
(b) the applicant submits to the Minister all additional information or samples requested under section 15;
(c) the applicant does not make a false or misleading statement in the application; and
(d) the issuance or amendment of the licence, as the case may be, is not likely to result in injury to the health of a purchaser or consumer.

Product Number

8. (1) The Minister shall assign a product number to each natural health product in respect of which a product licence is issued.

(2) In the case of a natural health product that is a drug for which a drug identification number is assigned in accordance with subsection C.01.014.2(1) of the *Food and Drug Regulations*, the product number required under subsection (1) shall be the drug identification number.

Refusal to Issue or Amend

9. (1) If the Minister refuses to issue or amend a product licence, the Minister shall send the applicant a notice that sets out the reason for the refusal.

(2) Within 30 days after the day on which the notice is sent, the applicant may make a request that the Minister reconsider the application.

(3) If the applicant makes a request in accordance with subsection (2), the Minister shall

(a) give the applicant an opportunity to be heard in respect of the application; and
(b) reconsider the application after giving the applicant that opportunity.

10. (1) After reconsidering the application, the Minister shall issue or amend the product licence if the requirements of section 7 are met.

(2) If the Minister again refuses to issue or amend the product licence, the Minister shall send the applicant a final notice that sets out the reason for the refusal.

Amendment

11. (1) If the licensee makes any of the following changes in respect of the natural health product, the licensee shall not sell any lot or batch of the natural health product affected by the change unless the product licence is amended accordingly:

(a) a change to its recommended dose;
(b) a change to its recommended duration of use;
(c) the deletion or modification of risk information shown on any of its labels, including the deletion or modification of a caution, warning, contra-indication or known adverse reaction associated with its use;
(d) a change of its recommended use or purpose;
(e) a change of the source material of any of its medicinal ingredients;
(f) changing any of its medicinal ingredients to or from being synthetically manufactured;
(g) a change to the potency of any of its medicinal ingredients;
(h) a change affecting its safety or efficacy that does not arise as a result of
  (i) a change to the quantity of a medicinal ingredient per dosage unit,
  (ii) the addition or substitution of a medicinal ingredient,
  (iii) a change to its dosage form, or
  (iv) a change to its recommended route of administration; or
(i) one or more of the following changes to its specifications, namely,
  (i) the removal of a test method set out in the specifications,
  (ii) the modification of a test method set out in the specifications in a manner that widens the purity tolerances of the natural health product or the quantity, identity or potency tolerances of any of its medicinal ingredients, or
  (iii) the modification of a test method set out in the specifications in a manner that renders it less precise, accurate, specific or sensitive.

(2) An application to amend a product licence shall be submitted to the Minister and shall contain the following information and documents:

(a) the product number of the natural health product;
(b) a statement identifying each change described in subsection (1) that has been made;
(c) information demonstrating that the natural health product is safe and efficacious after the change;
(d) the text of each label to be used in conjunction with the natural health product after the change, if the change is any of those described in paragraphs (1)(a) to (h); and
(e) a copy of the revised specifications, if the change is any of those described in paragraph (1)(g) or (i).

Notification

12. (1) If the licensee makes any of the changes described in subsection (2) in respect of the natural health product, the licensee shall, within 60 days after the day on which the change is made,

(a) notify the Minister of the change; and
(b) provide the Minister with the text of each label used in conjunction with the natural health product since the change, if the change is any of those described in paragraphs (2)(d) to (f).

(2) For the purposes of subsection (1), changes in respect of a natural health product are

(a) a change to any of the information submitted under paragraph 5(a) or (b);
(b) a change to any of the information provided under section 22;
(c) the addition or substitution of a non-medicinal ingredient, the addition or substitution of which does not affect its safety or efficacy;
(d) its sale under a brand name other than one submitted under paragraph 5(e);
(e) a change of the common or proper name of any of its medicinal ingredients; and
(f) the addition of risk information to any of its labels, including the addition of a caution, warning, contra-indication or known adverse reaction associated with its use.

Fundamental Change

13. For greater certainty, if the licensee makes any of the following fundamental changes in respect of the natural health product, the licensee may not sell the natural health product affected by the change unless a product licence is issued in accordance with section 7 for the natural health product as changed:

(a) a change to the quantity of a medicinal ingredient per dosage unit;
(b) the addition or substitution of a medicinal ingredient;
(c) a change to its dosage form; or
(d) a change to its recommended route of administration.

Licence Contents

14. (1) A product licence shall set out the following information:

(a) the name and address of the licensee;
(b) the product number of the natural health product;
(c) the dosage form that is authorized for the natural health product;
(d) the recommended route of administration that is authorized for the natural health product;
(e) the recommended dose that is authorized for the natural health product;
(f) the recommended duration of use, if any, that is authorized for the natural health product;
(g) in respect of each medicinal ingredient of the natural health product
  (i) its authorized quantity per dosage unit,
  (ii) its authorized potency, if any, and
  (iii) its authorized source material;
(h) the recommended use or purpose that is authorized for the natural health product; and
(i) the date on which the licence was issued.

(2) Within 60 days after the day on which the product licence is issued, the licensee shall notify the Minister of any information set out on the licence that the licensee knows to be incorrect.

Additional Information or Samples

15. If the information and documents submitted in respect of a product licence application under section 5 or an application for amendment under subsection 11(2) are insufficient to enable the Minister to determine whether the product licence should be issued or amended, as the case may be, the Minister may request that the applicant provide such additional information or samples of the natural health product as are necessary to make the determination.

Safety Information

16. If the Minister has reasonable grounds to believe that a natural health product may no longer be safe when used under the recommended conditions of use, the Minister may request that the licensee provide the Minister, within 15 days after the day on which the request is received, with information and documents demonstrating that the natural health product is safe when used under the recommended conditions of use.

Direction to Stop Sale

17. (1) The Minister may direct the licensee, manufacturer, importer and distributor to stop their sale of a natural health product if

(a) the licensee does not, within the required period, provide the Minister with the information and documents requested under section 16;
(b) the information and documents provided by the licensee in accordance with section 16 do not demonstrate that the natural health product is safe when used under the recommended conditions of use;

(c) in the case of a natural health product that is imported, the Minister has reasonable grounds to believe that the natural health product is not manufactured, packaged, labelled, imported, distributed or stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3;
(d) in the case of a natural health product that is not imported, the Minister has reasonable grounds to believe that the natural health product is not manufactured, packaged, labelled, distributed or stored in accordance with the requirements set out in Part 3; or
(e) the Minister has reasonable grounds to believe that the natural health product is not packaged or labelled in accordance with the requirements set out in Part 5.

(2) The Minister shall lift a direction to stop the sale of a natural health product if the licensee provides the Minister with information and documents demonstrating that

(a) in the case of a direction to stop sale arising under either paragraph (1)(a) or (b), the natural health product is safe when used under the recommended conditions of use;
(b) in the case of a direction to stop sale arising under paragraph (1)(c), the natural health product is manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3;
(c) in the case of a direction to stop sale arising under paragraph (1)(d), the natural health product is manufactured, packaged, labelled, distributed and stored in accordance with the requirements set out in Part 3;
(d) in the case of a direction to stop sale arising under paragraph (1)(e), the natural health product is packaged and labelled in accordance with the requirements of Part 5; or
(e) the situation giving rise to the direction to stop the sale of the natural health product did not exist.

Suspension and Cancellation

18. (1) Subject to subsection (2), the Minister may suspend a product licence if the Minister has reasonable grounds to believe that

(a) the licensee has contravened these Regulations or any provision of the Act relating to the natural health product; or
(b) the licensee has made a false or misleading statement in the application submitted under section 5 or the application for amendment under subsection 11(2).

(2) Subject to section 19, the Minister shall not suspend a product licence unless

(a) the Minister has sent the licensee a notice that sets out the reason for the intended suspension; and
(b) the licensee has not, within 90 days after the day on which the notice referred to in paragraph (a) is received, provided the Minister with information or documents demonstrating that the licence should not be suspended on the grounds that
  (i) the situation giving rise to the intended suspension did not exist, or
  (ii) the situation giving rise to the intended suspension has been corrected.

19. The Minister shall suspend a product licence before giving the licensee an opportunity to be heard if, as a result of any circumstance, the Minister has reasonable grounds to believe that it is necessary to do so to prevent injury to the health of a purchaser or consumer.

20. If the Minister suspends a product licence under section 18 or 19, the Minister shall send the licensee a notice that sets out the reason for the suspension and the day on which the suspension is effective, and the Minister shall

(a) reinstate the licence if, within 90 days after the day on which the suspension is effective, the licensee provides the Minister with information or documents demonstrating that the situation giving rise to the suspension did not exist or that it has been corrected; or
(b) cancel the licence if, within 90 days after the day on which the suspension is effective, the licensee has not provided the Minister with the information or documents referred to in paragraph (a).

21. (1) If the Minister cancels a licence under paragraph 20(b), the Minister shall send the licensee a notice that sets out the reason for the cancellation and the day on which the cancellation is effective.

Site Information

22. (1) Subject to subsection (2), the licensee shall provide the Minister with the following information prior to commencing the sale of the natural health product:

(a) in respect of each manufacturer, packager, labeller and importer of the natural health product
  (i) the person's name, address and telephone number, and if applicable, the person's facsimile number and electronic mail address, and
  (ii) if the person conducts the activity in Canada, the number assigned to the site licence issued in respect of that activity;
(b) the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of each distributor of the natural health product;
(c) the address of each building in which the natural health product is manufactured, packaged or labelled;
(d) the address of each building in which the natural health product is stored for the purposes of importation or distribution; and
(e) if the natural health product is imported, evidence demonstrating that the natural health product will be manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3.

(2) If the natural health product is one in respect of which a drug identification number is assigned in accordance with subsection C.01.014.2(1) of the *Food and Drug Regulations* and at the time the product licence is issued in respect of the natural health product it is already being sold, the licensee shall provide the information referred to in subsection (1) within 30 days after the day on which the product licence is issued.

Records

23. (1) Every licensee who sells a natural health product shall maintain the following records:

(a) a list of all ingredients contained in each lot or batch of the natural health product that has been made available for sale; and
(b) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale.

(2) The records shall be maintained by the licensee for a period of one year following the expiry date of the natural health product to which that record relates.

Reaction Reporting

24. (1) A licensee shall provide the Minister with

(a) a case report for each serious adverse reaction to the natural health product that occurs inside Canada, within 15 days after the day on which the licensee becomes aware of the reaction; and
(b) a case report for each serious unexpected adverse reaction to the natural health product that occurs inside or outside Canada, within 15 days after the day on which the licensee becomes aware of the reaction.

(2) A licensee who sells a natural health product shall annually prepare and maintain a summary report that contains a concise and critical analysis of

(a) all adverse reactions to the natural health product that have occurred inside Canada; and
(b) all reactions for which a case report is required to be provided under subsection (1), that have occurred
  (i) during the previous 12 months, and
  (ii) at a dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying organic functions in humans.

(3) If after reviewing a case report provided under subsection (1) or after reviewing any other safety data relating to the natural health product, the Minister has reasonable grounds to believe that the natural health product may no longer be safe when used under the recommended conditions of use, the Minister may request that, within 30 days after the day on which the request is received, the licensee

(a) provide to the Minister a copy of any summary report prepared under subsection (2); or
(b) prepare and provide to the Minister an interim summary report containing a concise and critical analysis of
    (i) all adverse reactions to the natural health product that have occurred inside Canada, and
    (ii) all reactions for which a case report is required to be provided under subsection (1), that have occurred
        (A) since the date of the most recent summary report prepared under subsection (2), and
        (B) at a dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying organic functions in humans.

Recall Reporting

25. Every licensee who commences a recall of a natural health product shall provide the Minister with the information referred to in section 62 within three days after the day on which the recall is commenced.

PART 2

SITE LICENCES

Application

26. This Part does not apply to any activity that is conducted in respect of a natural health product solely for the purposes of a clinical trial as defined in section 63.

Prohibition

27. (1) Subject to subsection (2), no person shall manufacture, package, label or import a natural health product for sale unless

(a) the person holds a site licence issued in respect of the activity; and
(b) the person conducts the activity in accordance with the requirements set out in Part 3.

(2) No person who holds a site licence shall manufacture, package, label or import a natural health product for sale

(a) during the period of any suspension of the licence under section 39 or 40; or
(b) after cancellation of the licence under paragraph 41(b).

Licence Application

28. An application for a site licence shall be submitted to the Minister and shall contain the following information and documents:

(a) the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant;
(b) a statement specifying which one or more of the activities of manufacturing, packaging, labelling or importing the applicant is proposing to conduct;
(c) if the applicant is proposing to manufacture, package or label a natural health product, the address of each building in which each activity is proposed to be conducted;
(d) if the applicant is proposing to import a natural health product, the address of each building in which that natural health product is proposed to be stored;
(e) for each activity specified under paragraph (b), a statement indicating whether or not the applicant is proposing to conduct the activity in respect of a natural health product in sterile dosage form; and
(f) in respect of the buildings, equipment, practices and procedures used to conduct each activity specified under paragraph (b), a report from a quality assurance person demonstrating that they comply with the requirements set out in Part 3.

Issuance and Amendment

29. (1) The Minister shall issue or amend a site licence if

(a) the applicant submits an application to the Minister that is in accordance with section 28 or subsection 32(2), as the case may be;
(b) the applicant provides the Minister with all additional information requested under section 37; and
(c) the applicant does not make a false or misleading statement in the application.

(2) If the Minister issues a site licence, the Minister shall assign that licence a site licence number.

Refusal to Issue or Amend

30. (1) If the Minister refuses to issue or amend a site licence, the Minister shall send the applicant a notice that sets out the reason for the refusal.

(2) Within 30 days after the day on which the notice is sent, the applicant may make a request that the Minister reconsider the application.

(3) If the applicant makes a request in accordance with subsection (2), the Minister shall

(a) give the applicant an opportunity to be heard in respect of the application; and
(b) reconsider the application after giving the applicant that opportunity.

31. (1) After reconsidering the application, the Minister shall issue or amend the site licence if the requirements of subsection 29(1) are met.

(2) If the Minister again refuses to issue or amend the site licence, the Minister shall send the applicant a final notice that sets out the reason for the refusal.

Amendment

32. (1) A licensee shall not conduct any of the following activities unless the site licence is amended accordingly:

(a) conduct any activity for which a site licence is required that the licensee is not already authorized to conduct;
(b) if the licensee is authorized to manufacture, package or label a natural health product, conduct that activity in a building that is not one in which the conduct of that activity is authorized;
(c) if the licensee is authorized to import a natural health product, store a natural health product in a building that is not one in which the storage is authorized; or
(d) if the licensee is authorized to conduct an activity, but not already authorized to conduct it in respect of a natural health product in sterile dosage form, conduct the activity in respect of a natural health product in that form.

(2) An application to amend a site licence shall be submitted to the Minister and shall contain the following information and documents:

(a) the licence number;
(b) a statement that specifies each activity referred to in subsection (1) that the licensee is proposing to conduct; and
(c) a report from a quality assurance person demonstrating that the buildings, equipment, practices and procedures used in respect of each activity conducted by the licensee will remain in compliance with the requirements set out in Part 3.

Notification

33. If the licensee makes any of the following changes, the licensee shall notify the Minister of the change within 60 days after the day on which the change is made:

(a) a change to the information submitted under paragraph 28(a); and
(b) a change that substantially alters any building, equipment, practice or procedure in respect of which a report from a quality assurance person was submitted under paragraph 28(f).

Licence Contents

34. A site licence shall set out the following information:

(a) the name and address of the licensee;
(b) the site licence number;
(c) each activity that the licensee is authorized to conduct and a statement indicating whether the activity is authorized to be conducted in respect of a natural health product in sterile dosage form;
(d) if the licensee is authorized to manufacture, package or label a natural health product, the address of each building in which the licensee is authorized to conduct that activity; and
(e) if the licensee is authorized to import a natural health product, the address of each building in which the licensee is authorized to store that natural health product.

Expiry

35. (1) A site licence expires on the first anniversary of the day on which it was issued unless it is renewed in accordance with section 36.

(2) A site licence that is renewed in accordance with section 36 expires on the day on which the renewal period ends unless the licence is further renewed in accordance with section 36.

Renewal

36. (1) The Minister shall renew a site licence if

(a) the licensee submits a request to renew the licence to the Minister no later than 30 days before the day on which the licence expires;
(b) the licensee provides the Minister with all additional information requested under section 37; and
(c) the renewal of the licence is not likely to result in injury to the health of a purchaser or consumer.

(2) If the Minister renews a site licence, the Minister shall renew it for a period of

(a) one year, if on the next anniversary of the day on which the licence was issued, the licensee will have held the licence for a period of less than three years;
(b) two years, if on the next anniversary of the day on which the licence was issued, the licensee will have held the licence for a period of at least three years but less than nine years; or
(c) three years, if on the next anniversary of the day on which the licence was issued, the licensee will have held the licence for a period of nine years or more.

(3) A site licence renewal becomes effective on the day after the anniversary of the day on which the licence was issued.

Additional Information

37. If the information and documents submitted in respect of an application under section 28, an application for amendment under subsection 32(2) or a request for renewal under section 36 are insufficient to enable the Minister to determine whether the licence should be issued, amended or renewed, as the case may be, the Minister may request that the applicant provide the Minister with such additional information as is necessary to make the determination.

Relinquishment of Authorization

38. (1) A licensee may, by amendment of the site licence, relinquish any part of the authorization given to the licensee under this Part.

(2) An application to amend the site licence for the purposes of subsection (1) shall be submitted to the Minister and shall contain the following information and documents:

(a) a document, signed and dated by the licensee, that sets out the site licence number and that specifies each activity or, by address, each building, in respect of which the authorization is requested to be relinquished; and
(b) an attestation, signed and dated by a quality assurance person, stating that after the relinquishment, the buildings, equipment, practices and procedures used in respect of each activity conducted by the licensee will remain in compliance with the requirements set out in Part 3.

(3) The Minister shall amend the site licence as requested by the licensee in paragraph (2)(a) if the licensee provides the Minister with an application that is in accordance with subsection (2).

Suspension and Cancellation

39. (1) Subject to subsection (2), the Minister may suspend a site licence if the Minister has reasonable grounds to believe that

(a) the licensee has contravened any provision of the Act or these Regulations; or
(b) the licensee has made a false or misleading statement in the application submitted under section 28 or the application for amendment under subsection 32(2).

(2) Subject to section 40, the Minister shall not suspend a site licence unless

(a) the Minister has sent the licensee a notice that sets out the reason for the intended suspension; and
(b) the licensee has not, within 90 days after the day on which the notice referred to in paragraph (a) is received, provided the Minister with information or documents demonstrating that the licence should not be suspended on the grounds that
    (i) the situation giving rise to the intended suspension did not exist, or
    (ii) the situation giving rise to the intended suspension has been corrected.

40. The Minister shall suspend a site licence before giving the licensee an opportunity to be heard if, as a result of any circumstance, the Minister has reasonable grounds to believe that it is necessary to do so to prevent injury to the health of a purchaser or consumer.

41. If the Minister suspends a site licence under section 39 or 40, the Minister shall send the licensee a notice that sets out the reason for suspension and the day on which the suspension is effective, and the Minister shall

(a) reinstate the licence if, within 90 days after the day on which the suspension is effective, the licensee provides the Minister with information or documents demonstrating that the situation giving rise to the suspension did not exist or that it has been corrected; or
(b) cancel the licence if, within 90 days after the day on which the suspension is effective, the licensee has not provided the Minister with the information or documents referred to in paragraph (a).

42. If the Minister cancels a licence under paragraph 41(b), the Minister shall send the licensee a notice that sets out the reason for the cancellation and the day on which the cancellation is effective.

PART 3

GOOD MANUFACTURING PRACTICES

Prohibition

43. (1) Subject to subsection (2),no person shall sell a natural health product unless it is manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with this Part.

(2) A person may sell a natural health product that is manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with requirements that are equivalent to those set out in this Part if the natural health product is imported.

Specifications

44. (1) Every natural health product available for sale shall comply with the specifications submitted in respect of that natural health product under paragraph 5(i) and with every change to those specifications made by the product licence holder.

(2) The specifications shall contain the following information:

(a) detailed information respecting the purity of the natural health product, including statements indicating its purity tolerances;
(b) for each medicinal ingredient of the natural health product, detailed information respecting its quantity per dosage unit and its identity, including statements indicating its quantity and identity tolerances;
(c) if a representation relating to the potency of a medicinal ingredient is to be shown on a label of the natural health product, detailed information respecting the potency of the medicinal ingredient, including statements indicating its potency tolerances; and
(d) a description of the methods used for testing or examining the natural health product.

(3) The specifications and every change to those specifications shall be approved by a quality assurance person.

Premises

45. (1) Every natural health product shall be manufactured, packaged, labelled and stored in premises that are designed, constructed and maintained in a manner that permits the activity to be conducted under sanitary conditions, and in particular that

(a) permits the premises to be kept clean and orderly;
(b) permits the effective cleaning of all surfaces in the premises;
(c) permits the natural health product to be stored or processed appropriately;
(d) prevents the contamination of the natural health product; and
(e) prevents the addition of an extraneous substance to the natural health product.

(2) Every natural health product shall be stored under conditions that will maintain the quality and safety of the natural health product.

Equipment

46. Every natural health product shall be manufactured, packaged, labelled and stored using equipment that is designed, constructed, maintained, operated and arranged in a manner that

(a) permits the effective cleaning of its surfaces;
(b) permits it to function in accordance with its intended use;
(c) prevents it from contaminating the natural health product; and
(d) prevents it from adding an extraneous substance to the natural health product.

Personnel

47. Every natural health product shall be manufactured, packaged, labelled and stored by personnel who are qualified by education, training or experience to perform their respective tasks.

Sanitation Program

48. Every natural health product shall be manufactured, packaged, labelled and stored in accordance with a sanitation program that sets out

(a) procedures for effectively cleaning the premises in which the activity is conducted;
(b) procedures for effectively cleaning the equipment used in the activity;
(c) procedures for handling any substance used in the activity; and
(d) all requirements, in respect of the health, the hygienic behaviour and the clothing of the personnel who are involved in the activity, that are necessary to ensure that the activity is conducted in sanitary conditions.

Operations

49. Every natural health product shall be manufactured, packaged, labelled and stored in accordance with standard operating procedures that are designed to ensure that the activity is conducted in accordance with the requirements of this Part.

50. Every manufacturer, packager, labeller, importer and distributor shall establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of the natural health product that has been made available for sale.

Quality Assurance

51. (1) Every manufacturer, packager, labeller, importer and distributor shall

(a) have a quality assurance person who
  (i) is responsible for assuring the quality of the natural health product before it is made available for sale, and
  (ii) has the training, experience and technical knowledge relating to the activity conducted and the requirements of this Part; and
(b) investigate and record every complaint received in respect of the quality of the natural health product and, if necessary, take corrective action.

(2) Every natural health product shall be manufactured, packaged and labelled using only material that, prior to its use in the activity, has been approved for that use by a quality assurance person.

(3) Every natural health product shall be manufactured, packaged, labelled and stored using methods and procedures that, prior to their implementation, have been approved by a quality assurance person.

(4) Every lot or batch of a natural health product shall be approved by a quality assurance person before it is made available for sale.

(5) Every natural health product that is sold and subsequently returned to its manufacturer, packager, labeller, importer or distributor, as the case may be, shall be approved by a quality assurance person before that natural health product may be made available for resale.

Stability

52. Every manufacturer and every importer shall determine the period of time that, after being packaged for sale, the natural health product will continue to comply with its specifications when

(a) it is stored under its recommended storage conditions; or
(b) if it does not have recommended storage conditions, it is stored at room temperature.

Records

Manufacturers

53. Every manufacturer who sells a natural health product shall maintain the following records at the site at which the natural health product is manufactured:

(a) the master production document for the natural health product;
(b) a list of all ingredients contained in each lot or batch of the natural health product;
(c) records of any testing conducted in respect of a lot or batch of raw material used in the manufacture of the natural health product;
(d) records of any testing conducted in respect of a lot or batch of the natural health product;
(e) a copy of the specifications for each natural health product that is being manufactured at the site;
(f) records demonstrating that each lot or batch of the natural health product was manufactured in accordance with the requirements of this Part;
(g) a record of each determination made by the manufacturer in accordance with section 52 and the information that supports that determination;
(h) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;
(i) a list of all natural health products that are being manufactured at the site; and
(j) a copy of the sanitation program in use at the site.

Packagers

54. Every packager who sells a natural health product shall maintain the following records at the site at which the natural health product is packaged:

(a) records of any testing conducted in respect of the material used to package the natural health product;
(b) records demonstrating that each lot or batch of the natural health product was packaged in accordance with the requirements of this Part;
(c) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;
(d) a list of all natural health products that are being packaged at the site; and
(e) a copy of the sanitation program in use at the site.

Labellers

55. Every labeller who sells a natural health product shall maintain the following records at the site at which the natural health product is labelled:

(a) records demonstrating that each lot or batch of the natural health product was labelled in accordance with the requirements of this Part;
(b) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;
(c) a list of all natural health products that are being labelled at the site; and
(d) a copy of the sanitation program in use at the site.

Importers

56. Every importer who sells a natural health product shall maintain the following records:

(a) the master production document for the natural health product;
(b) a list of all ingredients contained in each lot or batch of the natural health product;
(c) records of any testing conducted in respect of a lot or batch of the natural health product;
(d) a copy of the specifications for the natural health product;
(e) a record of each determination made by the importer in accordance with section 52 and the information that supports that determination;
(f) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale; and
(g) a copy of the sanitation program in use by the importer.

Distributors

57. Every distributor shall maintain the following records at the site at which the natural health product is stored:

(a) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;
(b) a list of all natural health products that are being stored at the site; and
(c) a copy of the sanitation program in use at the site.

Record Maintenance

58. Every person required under this Part to maintain a record that relates to a lot or batch of a natural health product shall maintain that record for a period of one year following the expiry date of the natural health product to which that record relates.

Sterile Natural Health Products

59. Every natural health product that is intended to be sterile shall be manufactured and packaged
(a) in a separate and enclosed area;
(b) under the supervision of a person trained in microbiology; and
(c) using a method scientifically proven to ensure its sterility.

Ophthalmic Use

60. (1) Section C.01.064 of the *Food and Drug Regulations* applies in respect of natural health products except that it shall be read without reference to the words "or parenteral".

(2) Section C.01.065 of the *Food and Drug Regulations* applies in respect of natural health products except that it shall be read without reference to

(a) the words "or parenteral"; and
(b) the words "or to its common name if there is no proper name".

Lot or Batch Samples

61. (1) Subject to subsection (3), if the Minister has reasonable grounds to believe that a lot or batch of a natural health product made available for sale may result in injury to the health of a purchaser or consumer, the Minister may require the manufacturer, importer or distributor to provide a sample of that lot or batch.

(2) The sample shall be of sufficient quantity to enable a determination of whether the lot or batch of the natural health product complies with the specifications for that natural health product.

(3) The Minister shall not require a sample of a lot or batch referred to in subsection (1) to be provided if more than one year has elapsed since the expiry date of that natural health product.

Recall Reporting

62. Every manufacturer, importer or distributor who commences a recall of a natural health product shall provide the Minister with the following information in respect of that natural health product within three days after the day on which the recall is commenced:

(a) the proper name and the common name of each medicinal ingredient that it contains;
(b) each brand name under which it is sold;
(c) its product number;
(d) the number of each lot or batch recalled;
(e) the name and address of each manufacturer, importer and distributor of the natural health product;
(f) the reasons for commencing the recall;
(g) the quantity manufactured or imported into Canada;
(h) the quantity that was distributed in Canada;
(i) the quantity remaining in the possession of each manufacturer, importer and distributor of the natural health product; and
(j) a description of any other action that the manufacturer, importer or distributor, as the case may be, is taking in respect of the recall.

PART 4

CLINICAL TRIALS INVOLVING HUMAN SUBJECTS

Interpretation

63. The following definitions apply in this Part.

"**adverse event**" means any adverse occurrence in the health of a clinical trial subject who is administered a natural health product, that may or may not be caused by the administration of the natural health product, and includes an adverse reaction, a serious adverse reaction and a serious unexpected adverse reaction. (*incident thérapeutique*)

"**clinical trial**" means an investigation in respect of a natural health product that involves human subjects and that is intended to discover or verify its clinical, pharmacological or pharmacodynamic effects, to identify and adverse events that are related to its use, to study its absorption, distribution, metabolism and excretion, or to ascertain its safety or efficacy. (*essai clinique*)

"**good clinical practices** " means generally accepted clinical practices that are designed to ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons, and the good clinical practices referred to in section 74. (*bonnes pratiques cliniques*)

"**import**" means to import a natural health product into Canada for the purpose of sale in a clinical trial. (*importer*)

"**investigator's brochure**" means a document containing the pre-clinical and clinical information in respect of the natural health product that is described in paragraph 66(e). (*brochure du chercheur*)

"**protocol**" means a document that describes the objectives, design, methodology, statistical considerations and organization of a clinical trial. (*protocole*)

"**qualified investigator**" means the person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where the clinical trial site is located and who is

(a) in the case of a clinical trial respecting a natural health product to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and

(b) in any other case, a physician and a member in good standing of a professional medical association. (*chercheur qualifié*)

"**research ethics board**" means a body that is not affiliated with the sponsor, and

(a) the principal mandate of which is to approve the initiation of, and conduct periodic reviews of, biomedical research involving human subjects in order to ensure the protection of their rights, safety and well-being; and

(b) that has at least five members, that has a majority of members who are Canadian citizens or permanent residents under the *Immigration Act*, that is composed of both men and women and that includes at least

(i) two members whose primary experience and expertise are in a scientific discipline, who have broad experience in the methods and areas of research to be approved and one of whom is from a medical discipline or, if the clinical trial is in respect of a natural health product to be used for dental purposes only, is from a medical or dental discipline,

(ii) one member knowledgeable in complementary or alternative health care,

(iii) one member knowledgeable in ethics,

(iv) one member knowledgeable in Canadian laws relevant to the research to be approved,

(v) one member whose primary experience and expertise are in a non-scientific discipline, and

(vi) one member who is from the community or is a representative of an organization interested in the areas of research to be approved and who is not affiliated with the sponsor or the site where the clinical trial is to be conducted. (*comité d'éthique de la recherche*)

"**sponsor**" means an individual, corporate body, institution or organization that conducts a clinical trial. (*promoteur*)

Application

64. (1) Subject to subsection (2), this Part applies to the sale or importation of natural health products to be used for the purposes of clinical trials involving human subjects.

(2) Except for paragraph 65(1)(a), subsection 65(2), section 68, paragraphs 74(a) to (i), subsections 75(1) and 76(1) and (2), paragraphs 76(3)(a) to (d) and (f) to (h), subsection 76(4) and sections 77 and 80 to 83, this Part does not apply to the sale or importation of a natural health product for the purposes of a clinical trial authorized under section 68.

Prohibition

65. (1) Despite section 4 and subject to subsection (2), no person shall sell or import a natural health product for the purposes of a clinical trial unless

(a) the person is authorized under this Part;
(b) the person complies with this Part and section C.01.064 of the *Food and Drug Regulations*; and
(c) if the natural health product is to be imported, the person has a representative in Canada who is responsible for the sale of the natural health product.

(2) No person shall sell a natural health product for the purposes of a clinical trial

(a) during the period of any suspension of the authorization under section 80 or 81; or
(b) after cancellation of the authorization under paragraph 82(b).

Application for Authorization

66. An application by a sponsor for authorization to sell or import a natural health product for the purposes of a clinical trial shall be submitted to the Minister and shall contain the following information and documents:

(a) a copy of the protocol for the clinical trial;
(b) a copy of the statement, as it will be set out in each informed consent form, that states the risks and anticipated benefits arising to the health of clinical trial subjects as a result of their participation in the clinical trial;
(c) a clinical trial attestation, signed and dated by the sponsor, containing
  (i) the title of the protocol and the clinical trial number,
  (ii) the brand name or the code for the natural health product,
  (iii) for each medicinal ingredient of the natural health product
    (A) the proper name and common name of the ingredient, and
    (B) the quantity of the ingredient per dosage unit of the natural health product,
  (iv) a qualitative list of the non-medicinal ingredients of the natural health product,
  (v) the dosage form of the natural health product,
  (vi) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the sponsor,
  (vii) if the natural health product is to be imported, the name, address and telephone number, and, if applicable, the facsimile number and electronic mail address of the sponsor's representative in Canada who is responsible for the sale of the natural health product,
  (viii) the address of each clinical trial site,
  (ix) for each clinical trial site, the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the qualified investigator,
  (x) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved the protocol referred to in paragraph (a) and approved an informed consent form containing the statement referred to in paragraph (b),
  (xi) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of any research ethics board that has previously refused to approve the protocol referred to in paragraph (a), its reasons for doing so and the date on which the refusal was given, and
  (xii) a statement
    (A) that the clinical trial will be conducted in accordance with good clinical practices and these Regulations, and
    (B) that all information contained in, or referenced by, the application is complete and accurate and is not false or misleading;
(d) an attestation, signed and dated by the research ethics board for each clinical trial site, that it has reviewed and approved the protocol referred to in paragraph (a) and an informed consent form containing the statement referred to in paragraph (b) and that the board carries out its functions in a manner consistent with good clinical practices;

(e) an investigator's brochure that contains the following information, namely,
  (i) the physical, chemical and, if any, the pharmaceutical properties of the natural health product,
  (ii) the chemistry and manufacturing information of each synthetically manufactured medicinal ingredient of the natural health product,
  (iii) the pharmacological properties of the natural health product, including its metabolites in all animal species tested, if any,
  (iv) the pharmacokinetics of the natural health product and the natural health product metabolism, including the biological transformation of the natural health product in all animal species tested, if any,
  (v) the toxicological effects in any animal species tested under a single dose study, a repeated dose study or a special study in respect of the natural health product, if any,
  (vi) the results of carcinogenicity studies in any animal species tested in respect of the natural health product, if any,
  (vii) the results of clinical pharmacokinetic studies of the natural health product, if any,
  (viii) the information regarding natural health product safety, pharmacodynamics, efficacy and dose responses of the natural health product that were obtained from previous clinical trials in humans, if any,
  (ix) the known contra-indications for and the precautions to be taken in respect of the natural health product, and
  (x) the recommended treatment in the event of an overdose of the natural health product, if any; and
(f) the proposed date for the commencement of the clinical trial at each clinical trial site.

Authorization

67. (1) The Minister shall authorize a sponsor to sell or import a natural health product for the purposes of a clinical trial if

(a) the sponsor submits an application to the Minister that is in accordance with section 66;
(b) the sponsor provides the Minister with all additional information or samples requested under section 73; and
(c) the Minister has reasonable grounds to believe, based on an assessment of the application, an assessment of any samples or information provided under section 73 or a review of any other information that
  (i) the use of the natural health product for the purposes of the clinical trial will not endanger the health of a clinical trial subject or other person,
  (ii) the clinical trial is not contrary to the best interests of the clinical trial subjects, and
  (iii) the objectives of the clinical trial will be achieved.

(2) The Minister shall authorize the sponsor to sell or import a natural health product for the purposes of a clinical trial by sending the sponsor a notice of the authorization.

68. A sponsor is authorized to sell or import a natural health product for the purposes of a clinical trial if the clinical trial is in respect of a recommended use or purpose for which that natural health product is issued a product licence.

Commencement Notice

69. The sponsor shall notify the Minister of the date on which the sale or importation of a natural health product for the purposes of a clinical trial will commence at a clinical trial site at least 15 days before the day on which that sale or importation commences.

Notification

70. If the sale or importation of a natural health product for the purposes of a clinical trial is authorized under this Part, the sponsor may make one or more of the following changes if the sponsor provides the Minister with notification of the change within 15 days after the day on which the change is made:

(a) a change to the information referred to in subparagraph 66(e)(ii) that does not affect the quality or safety of the natural health product; and
(b) a change to the protocol that does not alter the risk to the health of a clinical trial subject, other than a change for which an amendment is required by section 71.

Amendment

71. (1) Subject to subsection (2), if the sale or importation of a natural health product for the purposes of a clinical trial is authorized under this Part, the sponsor may not make any of the following amendments unless the authorization is amended accordingly:

(a) an amendment to the protocol that affects the selection, monitoring or dismissal of a clinical trial subject;
(b) an amendment to the protocol that affects the evaluation of the clinical efficacy of the natural health product;
(c) an amendment to the protocol that alters the risk to the health of a clinical trial subject;
(d) an amendment to the protocol that affects the safety evaluation of the natural health product;
(e) an amendment to the protocol that extends the duration of the clinical trial; and
(f) an amendment to the information referred to in subparagraph 66(e)(ii) that may affect the safety or quality of that natural health product.

(2) If the sponsor is required to immediately make one or more of the amendments referred to in subsection (1) because the clinical trial or the use of the natural health product for the purposes of the clinical trial endangers the health of a clinical trial subject or other person, the sponsor may immediately make the amendment and shall provide the Minister with the information referred to in subsection (3) within 15 days after the day on which the amendment is made.

(3) An application by the sponsor to amend the authorization for the sale or importation of a natural health product under this Part shall be submitted to the Minister and, in addition to a reference to the application submitted under section 66, shall contain the following information and documents:

(a) if as a result of the amendment it is necessary to amend the statement referred to in paragraph 66(b),
  (i) a copy of the amended statement that indicates the new information, and
  (ii) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved the amended statement;
(b) if the application is in respect of an amendment referred to in any of paragraphs (1)(a) to (e),
  (i) a copy of the amended protocol that indicates the amendment,
  (ii) a copy of the protocol submitted under paragraph 66(a),
  (iii) the rationale for the amendment,
  (iv) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved the amended protocol, and
  (v) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of any research ethics board that has previously refused to approve any amendment to the protocol, its reasons for doing so and the date on which the refusal was given;
(c) if the application is in respect of an amendment referred to in paragraph (1)(e), a copy of the amended investigator's brochure or an addendum to the investigator's brochure that indicates the new information, including supporting toxicological studies and clinical trial safety data, if any; and
(d) if the application is in respect of an amendment referred to in paragraph (1)(f), a copy of the amended chemistry and manufacturing information that indicates the amendment, and the rationale for that amendment.

(4) The Minister shall amend the authorization to sell or import a natural health product for the purposes of a clinical trial if

(a) the sponsor submits an application for amendment to the Minister that is in accordance with subsection (3);
(b) the sponsor provides the Minister with all additional information or samples requested under section 73; and
(c) the Minister has reasonable grounds to believe, based on an assessment of the application for amendment, an assessment of any samples or information submitted under section 73 or a review of any other information that
  (i) the use of the natural health product for the purposes of the clinical trial will not endanger the health of a clinical trial subject or other person, and
  (ii) the clinical trial is not contrary to the best interests of the clinical trial subjects.

(5) The Minister shall amend the authorization to sell or import a natural health product for the purposes of a clinical trial by sending the sponsor a notice of the amendment.

72. If the authorization to sell or import a natural health product for the purposes of the clinical trial is amended in accordance with subsection 71(5), the sponsor shall

(a) before commencing to sell or import the natural health product in accordance with the amended authorization
  (i) cease to sell or import the natural health product in accordance with the existing authorization, and
  (ii) maintain records concerning the information referred to in subparagraph 66(c)(ix), if any of that information has changed since it was submitted, and the information referred to in paragraph 66(f); and
(b) conduct the clinical trial in accordance with the amended authorization.

Additional Information and Samples

73. If the information and documents submitted in respect of an application under section 66 or an application for amendment under subsection 71(3) are insufficient to enable the Minister to determine whether the sale or importation of the natural health product should be authorized or whether the authorization should be amended, as the case may be, the Minister may request that the sponsor provide the Minister with samples of the natural health product or additional information relevant to the natural health product or the clinical trial that are necessary to make the determination.

Sponsor's Obligations

Good Clinical Practices

74. Every sponsor shall ensure that a clinical trial is conducted in accordance with good clinical practices and, without limiting the generality of the foregoing, shall ensure that

(a) the clinical trial is scientifically sound and clearly described in a protocol;
(b) the clinical trial is conducted, and the natural health product is used, in accordance with the protocol and this Part;
(c) systems and procedures that assure the quality of every aspect of the clinical trial are implemented;
(d) for each clinical trial site, the approval of a research ethics board is obtained before the clinical trial begins at the site;
(e) at each clinical trial site, there is no more than one qualified investigator;
(f) at each clinical trial site, medical care and medical decisions, in respect of the clinical trial, are under the supervision of the qualified investigator;
(g) each individual involved in the conduct of the clinical trial is qualified by education, training and experience to perform his or her respective tasks;
(h) written informed consent, given in accordance with the applicable laws governing consent, is obtained from every person before that person participates in the clinical trial but only after that person has been informed of
  (i) the risks and anticipated benefits to his or her health arising from participation in the clinical trial, and
  (ii) all other aspects of the clinical trial that are necessary for that person to make the decision to participate in the clinical trial;
(i) the requirements respecting information and records set out in section 76 are met; and
(j) the natural health product is manufactured and stored in accordance with the requirements set out in Part 3 except for section 61.

Labelling

75. (1) The sponsor shall ensure that the natural health product bears a label that sets out the following information in both official languages:

(a) a statement indicating that the natural health product is an investigational natural health product to be used only by a qualified investigator;
(b) the brand name or code of the natural health product;
(c) the expiry date of the natural health product;

(d) the recommended storage conditions for the natural health product, if any;
(e) the lot number of the natural health product;
(f) the name and address of the manufacturer;
(g) the name and address of the sponsor; and
(h) the protocol code or identification.

(2) Sections 86 to 94 do not apply to a natural health product used for the purposes of a clinical trial.

Records

76. (1) The sponsor shall record, handle and store all information in respect of a clinical trial in a way that allows its complete and accurate reporting as well as its interpretation and verification.

(2) The sponsor shall maintain complete and accurate records to establish that the clinical trial is conducted in accordance with good clinical practices and these Regulations.

(3) The sponsor shall maintain complete and accurate records in respect of the use of a natural health product in a clinical trial, including

(a) a copy of all versions of the investigator's brochure for the natural health product;
(b) records respecting each change made to the investigator's brochure, including the rationale for each change and documentation that supports each change;
(c) records respecting all adverse events in respect of the natural health product that have occurred inside or outside Canada, including information that specifies the dosage form and the use and purpose of the natural health product at the time of the adverse event;
(d) records respecting the enrolment of clinical trial subjects, including information sufficient to enable all clinical trial subjects to be identified and contacted in the event that the sale of the natural health product may endanger the health of the clinical trial subjects or other persons;
(e) records respecting the shipment, receipt, disposition, return and destruction of the natural health product;
(f) for each clinical trial site, an undertaking from the qualified investigator that is signed and dated by the qualified investigator prior to the commencement of his or her responsibilities in respect of the clinical trial, that states that
    (i) the qualified investigator will conduct the clinical trial in accordance with good clinical practices, and
    (ii) the qualified investigator will immediately, on discontinuance of the clinical trial by the sponsor, in its entirety or at a clinical trial site, notify both the clinical trial subjects and the research ethics board of the discontinuance, provide them with the reasons for the discontinuance and advise them in writing of any potential risks to the health of clinical trial subjects or other persons;
(g) for each clinical trial site, a copy of the protocol, informed consent form and any amendment to the protocol or informed consent form that have been approved by the research ethics board for that clinical trial site; and
(h) for each clinical trial site, an attestation, signed and dated by the research ethics board for that clinical trial site, stating that it has reviewed and approved the protocol and informed consent form and that the board carries out its functions in a manner consistent with good clinical practices.

(4) The sponsor shall maintain all records referred to in this Part for a period of 25 years.

Submission of Information and Samples

77. (1) The Minister shall require a sponsor to provide, within two days after the day on which the request is received, information concerning the natural health product or the clinical trial, or samples of the natural health product, if the Minister has reasonable grounds to believe that

(a) the use of the natural health product for the purposes of the clinical trial endangers the health of a clinical trial subject or other person;
(b) the clinical trial is contrary to the best interests of a clinical trial subject;
(c) a qualified investigator is not respecting the undertaking referred to in paragraph 76(3)(f); or
(d) information submitted or provided in respect of the natural health product or the clinical trial is false or misleading.

(2) The Minister may require the sponsor to provide, within seven days after the day on which the request is received, any information or records referred to in section 76, or samples of the natural health product, in order to assess the safety of the natural health product or the health of clinical trial subjects or other persons.

Reaction Reporting

78. (1) During the course of a clinical trial, the sponsor shall notify the Minister of any serious adverse reaction and any serious unexpected adverse reaction to the natural health product that has occurred inside Canada as follows:

(a) if it is neither fatal nor life threatening, within 15 days after the day on which the sponsor becomes aware of the information; and
(b) if it is fatal or life threatening, within seven days after the day on which the sponsor becomes aware of the information.

(2) The sponsor shall, within eight days after the day on which the Minister is notified under paragraph (1)(b), provide the Minister with a complete report in respect of that information that includes an assessment of the importance and implication of findings made.

Discontinuance of a Clinical Trial

79. (1) If the sponsor discontinues a clinical trial in its entirety or at a clinical trial site, the sponsor shall

(a) notify the Minister of the discontinuance within 15 days after the day of the discontinuance;
(b) provide the Minister with the reason for the discontinuance and its impact on the proposed or ongoing clinical trials in respect of the natural health product conducted in Canada by the sponsor;
(c) as soon as possible, notify all qualified investigators of the discontinuance and of the reasons for the discontinuance, and advise them in writing of any potential risks to the health of clinical trial subjects or other persons; and
(d) in respect of each discontinued clinical trial site, stop the sale or importation of the natural health product as of the day of the discontinuance and take all reasonable measures to ensure the recovery of all unused quantities of the natural health product that have been sold.

(2) If the sponsor discontinues a clinical trial in its entirety or at a clinical trial site, the sponsor may resume selling or importing the natural health product for the purposes of the clinical trial in its entirety or at the clinical trial site if, in respect of each clinical trial site where the sale or importation is to be resumed, the sponsor submits to the Minister the information referred to in subparagraphs 66(c)(ix) to (xi) and paragraphs 66(d) and (f).

Suspension and Cancellation

80. (1) Subject to subsection (2), the Minister may suspend the authorization to sell or import a natural health product for the purposes of a clinical trial, in its entirety or at a clinical trial site, if the Minister has reasonable grounds to believe that

(a) the sponsor has contravened these Regulations or any provisions of the Act relating to the natural health product;
(b) any information submitted or provided in respect of the natural health product or clinical trial is false or misleading;
(c) the sponsor has failed to comply with good clinical practices; or
(d) the sponsor has failed to
  (i) provide information or samples of the natural health product as required under section 73 or 77, or
  (ii) notify the Minister or provide a report under section 78.

(2) Subject to section 81, the Minister shall not suspend the authorization unless

(a) the Minister has sent the sponsor a notice that indicates whether the authorization is intended to be suspended in its entirety or at a clinical trial site and the reason for the intended suspension; and
(b) the sponsor has not, within 30 days after the day on which the notice referred to in paragraph (a) is received, provided the Minister with information or documents demonstrating that the authorization should not be suspended on the grounds that
  (i) the situation giving rise to the intended suspension did not exist, or
  (ii) the situation giving rise to the intended suspension has been corrected.

81. The Minister shall suspend the authorization to sell or import a natural health product for the purposes of a clinical trial, in its entirety or at a clinical trial site, before giving the sponsor an opportunity to be heard if, as a result of any circumstance, the Minister has reasonable grounds to believe that it is necessary to do so to prevent injury to the health of a clinical trial subject or other person.

82. If the Minister suspends the authorization under section 80 or 81, the Minister shall send the sponsor a notice that sets out the reasons for the suspension, the day on which the suspension is effective and indicating whether the authorization is suspended in its entirety or at a clinical trial site, and the Minister shall

(a) reinstate the authorization in its entirety or at a clinical trial site, as the case may be, if within 30 days after the day on which the suspension is effective the sponsor provides the Minister with information or documents demonstrating that the situation giving rise to the suspension did not exist or that it has been corrected; or

(b) cancel the authorization in its entirety or at a clinical trial site, as the case may be, if within 30 days after the day on which the suspension is effective the sponsor has not provided the Minister with the information or documents referred to in paragraph (a).

83. If the Minister cancels the authorization under paragraph 82(b), the Minister shall send the sponsor a notice that sets out the reason for the cancellation, the day on which the cancellation is effective and indicating whether the authorization is cancelled in its entirety or at a clinical trial site.

PART 5

GENERAL

Electronic Signatures

84. Any signature that is required by these Regulations to be shown on a record or document may be an electronic reproduction of the required signature.

Electronic Records

85. Any record that is required to be maintained by these Regulations may be maintained in any electronic format from which a printed copy of the record can be produced.

Labelling and Packaging

General

86. (1) No person shall a natural health product unless it is labelled and packaged in accordance with these Regulations.

(2) Despite subsection (1), a person may sell a natural health product that is not labelled and packaged in accordance with these Regulations if the sale is to a manufacturer or distributor.

87. (1) Subject to subsection (2), when required by these Regulations to be shown on a label, the following information respecting a natural health product shall be in both English and French:

(a) any of the information referred to in paragraphs (a) to (f) of the definition "recommended conditions of use" in subsection 1(1);

(b) the common name and proper name of each medicinal ingredient and each non-medicinal ingredient that it contains;

(c) a description of the source material of a medicinal ingredient; and

(d) its storage conditions.

(2) The common name or proper name of a medicinal ingredient or non-medicinal ingredient shall be shown in any other language if the name does not have an English or French equivalent.

88. The statements, information and declarations required by these Regulations to be shown on a label of a natural health product shall be

(a) clearly and prominently displayed; and
(b) readily discernible to the purchaser or consumer of the natural health product under the customary conditions of purchase and use.

89. If a natural health product has only one label, that label shall show all the statements, information and declarations required by these Regulations to be shown on both the inner and outer labels.

90. Every lot number required by these Regulations to be shown on a label of a natural health product shall be preceded by one of the following designations:

(a) "Lot number";
(b) "Lot No.";
(c) "Lot"; or
(d) "(L)".

91. Every product number required by these Regulations to be shown on a label of a natural health product shall

(a) in the case of a homeopathic medicine, be preceded by the designation "DIN-HM"; and
(b) in any other case, be preceded by the designation "NPN".

92. No reference, direct or indirect, to the Act, the *Food and Drug Regulations* or to these Regulations shall be made on any label of or in any advertisement for a natural health product unless the reference is specifically required by law.

93. (1) Subject to section 3 of the Act and section 94, the inner and outer labels shall show the following information in respect of a natural health product:

(a) on the principal display panel,
  (i) a brand name,
  (ii) its product number,
  (iii) its dosage form,
  (iv) if it is sterile, the words "sterile" and "stérile", and
  (v) the net amount in the immediate container in terms of weight, measure or number; and
(b) on any panel,
  (i) the name and address of the product licence holder,
  (ii) if it is imported, the name and address of the importer,
  (iii) the common name of each medicinal ingredient that it contains,
  (iv) the proper name of each medicinal ingredient it contains, but only if the proper name is not the chemical name,
  (v) a list by proper name, or by common name if the proper name is the chemical name, that sets out the quantity of each medicinal ingredient per dosage unit and, if any, the authorized potency of that medicinal ingredient,
  (vi) its recommended use or purpose,
  (vii) its recommended route of administration,
  (viii) its recommended dose,
  (ix) its recommended duration of use, if any,
  (x) its risk information including any cautions, warnings, contra-indications or known adverse reactions associated with its use,
  (xi) its recommended storage conditions, if any,
  (xii) its lot number,
  (xiii) its expiry date, and
  (xiv) a description of the source material of each medicinal ingredient that it contains.

(2) In addition to the requirements set out in subsection (1), the outer label shall show

(a) a qualitative list by common name, preceded by the words "non-medicinal ingredients", of all non-medicinal ingredients of the natural health product, and
(b) if the natural health product contains mercury or any of its salts or derivatives as a non-medicinal ingredient, a statement that sets out the quantity of mercury contained in the natural health product.

Small Package Labelling

94. (1) Subject to section 3 of the Act, the natural health product shall be labelled as follows if the immediate container is not large enough to accommodate an inner label that complies with the requirements of section 93:

(a) the inner label shall show the following in respect of the natural health product, namely,
  (i) a brand name,
  (ii) a qualitative list by proper name, or by common name if the proper name is the chemical name, that in descending order of quantity per dosage unit, sets out all medicinal ingredients that it contains,
  (iii) its recommended dose,
  (iv) its recommended duration of use, if any,
  (v) its lot number,
  (vi) its expiry date,
  (vii) its product number,
  (viii) if it is sterile, the words "sterile" and "stérile",
  (ix) the net amount in the immediate container in terms of weight, measure or number,
  (x) its recommended use or purpose, and
  (xi) if it does not have an outer label, a statement that refers the purchaser or consumer to the leaflet that is required in accordance with subsection (2); and
(b) the outer label, if any, shall be labelled as required under section 93.

(2) If the natural health product does not have an outer label, the statements, information and declarations required to be shown on the outer label under section 93 shall be shown in a leaflet that is affixed or attached to the immediate container.

Security Packaging

95. (1) Subject to subsection (2), no person shall sell or import a natural health product that is packaged unless the natural health product is contained in a security package.

(2) Subsection (1) does not apply to lozenges.

(3) Subject to subsection (4), a statement or illustration that draws attention to the security feature of the security package referred to in subsection (1) shall be shown

(a) on the inner label; and
(b) if the security feature is a part of the outer package, on the outer label.

(4) Subsection (3) does not apply if the security feature of a security package is self-evident and is an integral part of the immediate container.

Pressurized Containers

96. Sections A.01.061 to A.01.063 of the *Food and Drug Regulations* apply in respect of natural health products.

Cautionary Statements and Child Resistant Packages

97. Subsections C.01.001(2) to (4) and C.01.028(1), paragraphs C.01.028(2)(b) and (c), section C.01.029, subsection C.01.031(1), paragraphs C.01.031.2(1)(a) and (c) to (g), subsection C.01.031.2(2), and paragraphs C.01.031.2(3)(a) and (c) of the *Food and Drug Regulations* apply in respect of natural health products.

Medicinal Ingredient Representations

98. Section C.01.012 of the *Food and Drug Regulations* applies in respect of natural health products.

Inspectors

99. Sections A.01.022 to A.01.026 of the *Food and Drug Regulations* apply in respect of natural health products.

Imported Natural Health Products

100. In addition to these Regulations, sections A.01.040 to A.01.044 of the *Food and Drug Regulations* apply in respect of natural health products.

Export Certificates

101. Section A.01.045 of the *Food and Drug Regulations* and Appendix III to those Regulations apply in respect of natural health products.

Sampling of Articles

102. Sections A.01.050 and A.01.051 of the *Food and Drug Regulations* apply in respect of natural health products.

Tablet Disintegration Times

103. Subsection C.01.015(1) and paragraphs C.01.015(2)(d) to (f) of the *Food and Drug Regulations* apply in respect of natural health products.

Sale of Natural Health Product for Emergency Treatment

11-5-04

103.1 Sections C.08.010 and C.08.011 of the *Food and Drug Regulations* apply in respect of natural health products except that

(a) a reference in those sections to "new drug" shall be read as a reference to "natural health product"; and

(b) the reference in subsection C.08.011(1) of the *Food and Drug Regulations* to "section C.08.002" shall be read as a reference to "subsection 4(1) of the *Natural Health Products Regulations*".

PART 6

AMENDMENTS, TRANSITIONAL PROVISIONS AND COMING INTO FORCE

Amendments

Food and Drug Regulations

104. Section C.01.030 of the *Food and Drug Regulations* is repealed.

105. Division 4 of Part D of the Regulations is repealed.

106. Sections D.05.001 to D.05.007 of the Regulations are repealed.

107. Section D.05.010 of the Regulations is repealed.

Transitional Provisions

108. (1) Subject to section 110, a person may, without complying with these Regulations, sell a drug to which these Regulations apply that is assigned a drug identification number in accordance with section C.01.014.2(1) of the *Food and Drug Regulations*, until the earlier of

(a) the day on which an application for a product licence in respect of the drug is disposed of or withdrawn, and
(b) December 31, 2009.

(2) A person who sells a drug under subsection (1) shall conduct that sale in accordance with the requirements of the *Food and Drug Regulations*.

109. An application for a product licence that is made in respect of a drug referred to in subsection 108(1) on or before December 31, 2009 is not required to contain the information referred to in paragraph 5(g).

110. A sale or importation of a drug to which these Regulations apply that, before January 1, 2004, is authorized for the purposes of a clinical trial under Division 5 of Part C of the *Food and Drug Regulations* shall continue to be regulated under that Division.

111. Until December 31, 2009, a person may sell a lot or batch of a drug referred to in section 108 that is not labelled or packaged in accordance with the requirements of Part 5 if the lot or batch is packaged in accordance with the requirements of the *Food and Drug Regulations*.

112. If during the period beginning of January 1, 2004 and ending on December 31, 2005, the information referred to in section 22 is not available to the licensee prior to commencing the sale of the natural health product or within 30 days after the day on which the license is issued in respect of the natural health product, as the case may be, the licensee shall provide the information to the Minister immediately after it is available to the licensee.

113. (1) A person who, before January 1, 2004, manufactures, packages, labels or imports for sale a drug to which these Regulations apply may continue to conduct the activity in respect of that drug without complying with the requirements of Parts 2 and 3, until the earlier of

(a) the day on which that person's application for a site licence to conduct that activity in respect of the drug is disposed of or withdrawn, and
(b) December 31, 2005.

(2) A person who conducts an activity under subsection (1) shall conduct that activity in accordance with the requirements of the *Food and Drug Regulations*.

114. (1) A person who, before January 1, 2004, distributes a drug to which these Regulations apply may continue to conduct the activity in respect of that drug without complying with the requirements of Part 3 until December 31, 2005.

(2) A person who conducts an activity under subsection (1) shall conduct that activity in accordance with the requirements of Division 2 of Part C of the *Food and Drug Regulations*.

115. A person may sell a lot or batch of a drug referred to in section 108 that is not manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with the requirements of Part 3 if

(a) the lot or batch is manufactured, packaged and labelled before January 1, 2006; and
(b) any manufacturing, packaging, labelling, importation, distribution or storage of the lot or batch that is not conducted in accordance with the requirements of Part 3 is conducted in accordance with the requirements of Division 2 of Part C of the *Food and Drug Regulations*.

Coming into Force

116. (1) Except for section 6, these Regulations come into force on January 1, 2004.

(2) Section 6 comes into force on July 1, 2004.

SCHEDULE 1
(*Subsection 1*(1))

INCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1.	A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2.	An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3.	Any of the following vitamins: biotin folate niacin pantothenic acid riboflavin thiamine vitamin A vitamin B_6 vitamin B_{12} vitamin C vitamin D vitamin E vitamin K_1 vitamin K_2
4.	An amino acid
5.	An essential fatty acid
6.	A synthetic duplicate of a substance described in any of items 2 to 5
7.	A mineral
8.	A probiotic

4-10-05

SCHEDULE 2
(*Subsection 1*(1))

EXCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1.	A substance set out in Schedule C to the Act
2.	A substance set out in Schedule D to the Act, except for the following: (a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
3.	A substance regulated under the *Tobacco Act*
4.	A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*
5.	A substance that is administered by puncturing the dermis
6.	An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic

Definition

1. In these Regulations, "marihuana" means the substance referred to as "Cannabis (marihuana)" in subitem 1(2) of Schedule II to the *Controlled Drugs and Substances Act* other than marihuana sold or imported to be used for the purpose of a clinical trial, as that term is defined in section C.05.001 of the *Food and Drug Regulations*, involving human subjects.

Exemptions

2. Marihuana is exempt from the application of the *Food and Drugs Act* and the regulations made under it, other than these Regulations, if it is produced:

3-12-03

(a) under contract with Her Majesty in right of Canada; or
(b) under a designated-person production licence, as defined in subsection 1(1) of the *Marihuana Medical Access Regulations*.

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APPENDIX III

FORMS

Export Certificate

(Under the *Food and Drugs Act**--R.S.C. 1985, c.F-27)

The undersigned exporter hereby certifies that the (description of article) _____

_____

packaged and labelled as follows: _____

and marked in distinct overprinting with the word "Export"

1. is not manufactured for consumption in Canada,
2. is not sold for consumption in Canada, and
3. packages and the contents of such packages do not contravene any known requirement of the law of _____

(*name of country or countries*) to which it is or is about to be consigned.

Dated at _____, this _____ day of _____ 19

Canada: In the matter of an Export Certificate under the *Food and Drugs Act*,

Province of _____

To Wit: I, _____

of the _____ of _____

in the _____ of _____

do solemnly declare:

1. that I am the "Exporter" issuing the certificate above set out and have a knowledge of the matters and facts herein declared to by me,

   or

   I am the _____ of _____

   _____

   the "Exporter" issuing the certificate above set out and have a knowledge of the matters and facts herein declared to by me (describe position of declarant as the agent of the "Exporter" in case of a Corporation issuing the certificate),
2. that the information set out in the said certificate is true,
3. that all information relevant to the purpose of the said certificate is set out herein and no information relevant thereto has knowingly been withheld.

And I make this solemn declaration conscientiously believing it to be true, and knowing that it is of the same force and effect as if made under oath, and by virtue of *The Canada Evidence Act*.

Declared before me at _____ this _____ day of _____, 19

_____ _____

A commissioner for Taking Oaths

*See section 37 of the Food and Drugs Act and Appendix III of the *Food and Drug Regulations*